Evaluate Vantage

June 25, 2013

EP Vantage interview – JenaValve aims to triple sales or sell itself

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The advantages of getting to market with a world-first technology are well known. There is also a rationale, though, for a slightly craftier strategy where a company bides its time, developing a next-generation device, and enters the market at a point when it can take advantage of the interest built by its predecessors and pull the rug from under them.

“I’m always attracted to the underdog,” Raymond Cohen, chairman of the German heart valve company JenaValve Technology, tells *EP Vantage*. Having previously sold a business run along similar lines to a major medtech player, Mr Cohen hints at a similar outcome for JenaValve.

Second generation

JenaValve’s self-titled technology, used in transcatheter aortic valve implantation (TAVI), is a second-generation valve that the company hopes will take share from the market leaders despite being some years behind them.

The key to this approach, Mr Cohen says, is improving on what went before. First-generation valves, such as Edwards Lifesciences’ Sapien and Medtronic’s CoreValve, were prone to problems such as paravalvular leakage, where owing to poor positioning blood flows around the valve rather than through it, a direct correlate to mortality. In some cases poor placement also interfered with the heart’s native pacing ability, necessitating the subsequent implantation of a pacemaker.

These flaws were largely accepted at the time, Mr Cohen says. “People said, ‘That’s TAVI. It’s a great advancement compared with not being able to treat these patients, so we’re just going to accept that.’ It was just part of the deal.”

But no longer. “JenaValve has come up with a true second-generation device for TAVI,” Mr Cohen says, and points to the valve’s design as permitting better positioning, avoiding leakage and pacing problems. “The design of the product allows the device to be clamped onto the native leaflets, and it’s this clamping mechanism that allows you to get a really good seal. So whether you have a lot of calcification or a little, you can’t place the device too high or too low.”

The JenaValve product was CE marked in September 2011 for transapical delivery via an incision in the chest, but the first mover, Sapien, had already been in place for four years (*Therapeutic focus – Transcatheter aortic valves boosted by guidelines, October 1, 2012*).

It is selling well, Mr Cohen says, although it is still marketed only in Germany, Austria and Switzerland. “The company did something a little north of $5m in 2012 in its first full year, and will certainly double, if not triple, sales in 2013 as compared to 2012.”

This is solely with the transapical valve, but JenaValve is also working towards approval of a transfemoral system. A study to back CE marking will begin in the fourth quarter of 2013, and CE marking itself is expected around a year from now.

Around 35% of all TAVI procedures are done transapically and 65% transfemorally, Mr Cohen says, adding that JenaValve aims to take a 25% share of the European market “within a couple of years”.

Exit

It might be possible to gain a clue to the future of JenaValve from the activities of the company Mr Cohen used to run: Vessix Vascular. Like JenaValve, Vessix was active in one of the most exciting and fast-moving areas of medtech – renal denervation – and, again like JenaValve, it was aiming not to lead the pack but to be a “fast follower”.

Though Medtronic was the first company to market a renal denervation tech, Vessix’s follow-on device was sufficiently impressive to prompt Boston Scientific to buy it for $425m last autumn (*Boston Scientific*

gatecrashes renal denervation market with Vessix buy, November 9, 2012).

It seems possible that JenaValve might follow a similar path. “Every early-stage company that has venture capital investors would ultimately like to get an exit, and sooner rather than later. That’s just the modus operandi of all venture-backed companies,” says Mr Cohen.

“Second to that an IPO works too – certainly it’s a second choice to an exit, but now that the IPO market in Europe and the US is opening quite nicely there are opportunities for companies like JenaValve to be able to go public as well.”

Though Edwards, Medtronic, St. Jude Medical and the French firm Symetis all have CE-marked TAVI products, only the first two are racking up significant sales in Europe, Mr Cohen says. This means that St. Jude or Boston, whose Lotus valve is set for CE mark later this year, could theoretically be interested in buying JenaValve, as could Covidien or Abbott Laboratories, among others.

Though its goal of 25% market share seems somewhat optimistic for a relatively small player, JenaValve may not be the underdog for much longer.

CE marked transcatheter aortic valves		
Company	**Device Name**	**EU Approval (CE Mark)**
Edwards Lifesciences	Sapien	September 30, 2007
	Sapien XT	March 2, 2010
Medtronic	CoreValve	May 16, 2007
Symetis	Acurate TA	September 30, 2011
JenaValve Technology	JenaValve	September 30, 2011
St. Jude Medical	Portico	November 19, 2012

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