

Jenavalve set on US approval, but faces a fight for market share



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Smaller transcatheter aortic valve groups face a tricky future.

With many of Jenavalve Technology's former peers having been bought by larger cardiovascular-focused medtechs, the German group is in danger of looking like an also-ran in the transcatheter heart valve space. It has redoubled its efforts, however, and has started a new trial aimed at securing US approval for a new product.

It is, of course, not the only small private valve developer. Companies like Meril Life Sciences and Colibri Heart Valve are also plugging away; but at least one group, Direct Flow Medical, has folded, and with the US market occupied by Edwards Lifesciences and Medtronic the only realistic hope for Jenavalve and co is attracting a buyer.

Jenavalve's first device, also called Jenavalve, was CE marked in 2011 but never made it to the US; in 2012 the company's sales were around \$5m but, being private, it has not disclosed figures since.

The group appears to have given up on getting the Jenavalve device approved in the US. It has instead pivoted to a product called Everdur, and has started a trial with the goal of obtaining premarket approval. A single-arm early feasibility study of Everdur is to begin in New York and Washington, DC, testing the device in patients with symptomatic, severe aortic stenosis and symptomatic, severe aortic regurgitation for whom open surgery is an extreme or high risk.

This follows the initiation in June of a European study designed to secure CE mark for Everdur. Jenavalve reckons it could get the CE mark by the second half of next year; US approval will take years longer.

Too small

Everdur is unlike the handful of catheter-mounted aortic devices on the US market in that it is designed to treat patients with severe aortic regurgitation who are at increased surgical risk; this population has no transcatheter option at present.

But this device is still a long way from FDA approval, and even if it gets the nod it is not clear how much of an advantage this indication might prove in a market split between the two valve powerhouses, Edwards and Medtronic.

So entrenched are these two groups that for many years it has seemed that the only form of success available

to a smaller aortic valve company is a takeout; actually launching a device in the US and competing is all but impossible for smaller groups.

Symetis, for example achieved the only goal realistically available to it in early 2017 ([Boston buys Symetis and accelerates in aortic – but ditches mitral](#), March 30, 2017). Direct Flow, one of the other small groups aiming to contest the aortic market, ceased trading in November 2016.

This leaves Jenavalve with vanishingly few extant peers. Meril Lifesciences is best known for its bioresorbable stent technology, but it is also developing a transcatheter aortic valve called MyVal. And privately held Colibri Heart Valve is working on a valve also called Colibri. A search of [clinicaltrials.gov](#) fails to yield any US trials of these products, and neither appears to be CE marked.

The two US incumbents are due to see some competition this year – but not from Jenavalve or any other small company. Instead Abbott is expected to get a PMA for Portico, the valve it obtained when it bought St. Jude Medical. But by 2024 Abbott will lag Boston Scientific, whose Lotus valve could reach the US in 2019 – and neither group’s sales will even approach the leaders’.

The US transcatheter aortic valve market				
Company	US sales (\$m)			
	2018e	2020e	2022e	2024e
Edwards Lifesciences	1,360	1,738	2,113	2,479
Medtronic	644	828	1,025	1,222
Boston Scientific	0	104	251	381
Abbott Laboratories	7	56	137	168

Source: EvaluateMedTech.

As for Jenavalve, its best chance remains a buyout. It has had nearly \$170m in venture and debt financing since being founded in 2006, and stands very little chance of making this back unless someone steps in to buy it. The competitive landscape being what it is, it is not at all clear that anyone might want to.