Evaluate Vantage

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Boston has trouble delivering its valve

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Boston Scientific will not seek US approval for its Lotus Edge heart valve this year after all. Last-minute tests for the device have shown a design flaw related to the valve's delivery system, similar to the issue that caused sales and development of the aortic prosthesis to be put on hiatus in February.

US approval and launch mid-2018 was a key event for the company, and vital to the Lotus franchise's currently forecast 2022 sales of nearly $1bn. Investors understandably reacted to a postponement of as-yet unspecified length with horror, pushing Boston's shares down 7% yesterday.

On a conference call management declined to give a specific timing update for CE mark and FDA approval of the Lotus Edge. But investors will want it as soon as possible: Boston's previously outlined guidance of 6-8% organic revenue growth by 2019-20 still stands if Lotus reaches the US and gets back on the European market reasonably quickly.

But if the worst comes to the worst and Lotus is kaput the company will have to drop that range to 5-7% growth, said its chief executive, Michael Mahoney.

Reprise

The initial version of Lotus was approved in Europe four years ago but Boston opted not to bring this one to the US, instead focusing on a second-gen model, Lotus Edge. CE mark for the new valve was planned for the same middle of next year timeframe.

That changed nine months ago when Boston pulled Lotus from sale and both valves from clinical trials owing to premature release of a pin that affixes the valve to the delivery device (*No Lotus élan for Boston, February 24, 2017*). At the time it was running the Reprise III study, in which both versions of Lotus were pitted against Medtronic's CoreValve, which is approved in the US.

Data from Reprise III have been submitted to the FDA as part of Boston's still-incomplete approval application for Lotus Edge. And what must be particularly galling for the group is that these data were excellent, proving not just non-inferiority to CoreValve on safety but superiority on efficacy (*Lotus blooms in phase III, May 16, 2017*).

Boston's management said the current problem was distinct from, but related to, the earlier design flaw.

"We did resolve that early pin release," said Kevin Ballinger, president of Boston's interventional cardiology segment. "It's not that issue per se but … it is still part of that overarching umbrella of how the valve attaches to the delivery system."

Delivering

At least the company has a back-up, having obtained the Acurate Neo valve through the acquisition of the Swiss group Symetis in March. This is expected to enter US trials in the second half of next year, and the company is working with the FDA on trial design.

A large European study, Scope II, is under way. This is not an approval trial as Acurate Neo is already CE marked; rather it is designed to prove the valve's non-inferiority to CoreValve in the hope of boosting sales.

But Acurate Neo is years away from the US market, and if Boston is forced to rely on this for its US aortic valve sales it will come as a sore disappointment to investors who have been expecting a US market debut in the coming six months or so.

According to *EvaluateMedTech*'s sellside consensus, the Lotus franchise is forecast to bring in $966m in 2022, putting Boston reasonably close to Medtronic but some way behind Edwards Lifesciences.

If Lotus cannot be revived sales of the Symetis valve would not come close to replacing that near-billion. The same thing holds true commercially as clinically: the valve ought to work nicely – if it can be delivered.

The transcatheter aortic valve players									
		Global sales ($m)							
Company	**Device franchise**	**2016**	**2017e**	**2018e**	**2019e**	**2020e**	**2021e**	**2022e**	**CAG**
Edwards Lifesciences	Sapien	1,629	2,005	2,311	2,514	2,717	2,929	3,141	+12
Medtronic	CoreValve	855	1,073	1,123	1,209	1,318	1,421	1,524	+10
Boston Scientific	Lotus	82	57	199	403	595	796	996	+52
Abbott Laboratories*	Portico	31	59	57	75	117	184	251	+42
*Formerly St. Jude Medical. Source: EvaluateMedTech.									

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