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St. Jude not a lost cause, but still needs some miracles

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There is no doubt that St. Jude Medical had a tough 2015. A lack of key products has made it hard to compete with its cardiac rhythm management rivals and sales have suffered accordingly. This has in turn affected its share price putting the company, whose namesake is the patron saint of lost causes, among the top big-cap medtech fallers last year.

And even one of its supposed saviours, the CardioMEMS heart failure monitor, has fallen flat with Q4 sales declining and a second rejection from a regional US payer in February. CardioMEMS is now in limbo while St. Jude awaits a national US reimbursement decision, expected by the end of the year. This and other 2016 developments are crucial for the company – but don't call its current predicament a crisis, BMO Capital Markets analyst Joanne Wuensch told *EP Vantage*.

"A crisis would indicate to me that there is a problem with its business that cannot be fixed – for example accounting fraud or the risk of bankruptcy," Ms Wuensch said, adding that St. Jude is merely "stuck, or transitioning".

Even so, it might take a while to dig itself out of the hole it is in. St. Jude's cardiac rhythm management (CRM) division "probably won't get back to market growth rates until sometime in 2017", Jefferies analyst Raj Denhoy told *EP Vantage*.

And even that will not be much to write home about. "The CRM market isn't growing that much right now," he added. "We do see some unit growth but pricing has been under quite a bit of pressure."

Catalysts

Both analysts pinpointed several upcoming catalysts that could help propel St. Jude to better times. Firstly, there is the aforementioned US National Coverage Decision on CardioMEMS – but even if this is positive, "I don't think it will turn on a spigot and everything starts going fine from there on out", Ms Wuensch said.

Part of the problem, she believes, is "how do you change practice? How do you change from how you're currently monitoring these patients to a different methodology, even if it's a better methodology?"

And a positive reimbursement decision is not a given, said Mr Denhoy, who highlighted questions over the CardioMEMS pivotal data, which led to a split advisory panel vote on efficacy. "The FDA ultimately approved it, but I think a lot of these payers are saying: we still want to see more evidence that this is cost effective and clinically efficacious for our covered lives."

In spite of this, he does not believe that St. Jude will need to carry out another large study in order to get reimbursement.

MRI-compatible

But before the CardioMEMS decision, a couple of important products are expected to get FDA approval, among them an MRI-compatible pacemaker. One reason why St. Jude has fallen behind in CRM is a lack of MRI-safe devices, the analysts explained.

"The market has shifted, probably to a bigger degree than anyone expected, to these MRI-compatible devices," Mr Denhoy said. "And St. Jude has probably lost some hospital contracts because of its inability to sell these devices." He estimated that the company is a year to a year and a half behind its competitors, which include Medtronic and the German group Biotronik.

Approval of St. Jude's pacemaker is expected to be followed by the go-ahead for an MRI-compatible implantable cardioverter defibrillator (ICD) in the first half of 2017. These should at least put the company on a par with its rivals – but do not mean St. Jude will regain market share straight away.

"The CRM business is fairly sticky, so it is usually difficult for a manufacturer to lose a fair amount of share

unless there is a product recall, but it's also often difficult for a manufacturer to regain a lot of share," said Ms Wuensch.

Quad or multi?

Competition is also increasing in quadripolar leads, used in cardiac resynchronisation therapy for heart failure. St. Jude was once the leader of the field with the only approved device, but Medtronic had a quadripolar product approved in 2014 and Boston Scientific is expected to bring one out this year.

While conventional leads use two electrodes to stimulate the heart, quadripolar devices use four. This allows therapy to be personalised to each patient, making it more effective.

"Everybody's kind of in an equal position now, which isn't great for St. Jude, because that's been the source of a lot of growth for them," said Mr Denhoy.

However, St. Jude does have a trump card in the form of its multipoint technology, which the FDA approved in February. Multipoint technology goes a step further than quadripolar, allowing stimulation with multiple electrodes at any given time, making it even more flexible.

Whether that will give St. Jude the edge or whether quadripolar technology will be enough for physicians is currently unclear, Mr Denhoy said.

St. Jude Medical's key recent & upcoming catalysts	
Catalyst	**Date**
FDA approval of multipoint pacing technology	Approved February 2016
FDA approval of MRI-safe pacemaker	Expected H1 2016
FDA approval of Nanostim leadless pacemaker	Expected H2 2016
US National Coverage Decision on CardioMEMs	Expected end 2016
FDA approval of MRI-safe ICD	Expected H1 2017

It is clear that St. Jude has a lot on its plate – even without taking into account its Nanostim leadless pacemaker, also awaiting FDA approval, and the recent acquisition of left ventricular assist device developer Thoratec, which the analysts view as positives.

St. Jude has to take things step by step, Ms Wuensch believes. "Stocks change, companies change. It's not like they're in a hole that they can no longer be delivered from," she concluded. The company will be hoping she is right.

This article has been corrected to reflect the fact that approval of an MRI-compatible ICD is expected in H1 2017.

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