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St Jude banks on innovation to see it through tough times for medtech

Elizabeth Cairns

St Jude Medical has had a turbulent time of late. Good results for its renal denervation and fractional flow reserve technologies went some way to mitigating worrying findings on its Durata pacemaker leads, but the company's decision to cut 300 jobs and restructure its operations will see it change significantly in order to face new economic realities.

The reorganisation is mostly a reaction to the US medtech tax coming in to force at the beginning of next year. The industry-wide 2.3% excise levy will apply to device sales in the US after December 31, 2012, and will hit St Jude for $50-60m – exactly the amount the rejig is purportedly going to save.

St Jude – the 17th largest company by worldwide medtech sales, according to *EvaluateMedtech* – is going to combine its four current product divisions to create two new divisions. The cardiac rhythm management and neuromodulation sections will be folded together to form the implantable electronic systems division, and the cardiovascular and atrial fibrillation divisions will together make up the cardiovascular and ablation technologies group.

Coping strategies

The 300 job losses will come from IT, HR, legal, business development and marketing. Analysts view the decision to leave the sales division untouched as a positive, but retaining staffing levels in R&D is perhaps even more important.

Joanne Wuensch, an analyst at BMO, tells *EP Vantage* the restructure is a sensible move, given that the implantable cardioverter-defibrillator market has been, at best, flat worldwide and, while recovering, is still not robust. St Jude saw its pacemaker sales fall by 8.9% last quarter compared with the same period the previous year. "The markets they [St Jude] are participating in are weaker and therefore it creates an opportunity to right-size the organisation," Ms Wuensch says.

The new US medtech tax is not an issue unique to St Jude, of course, and staffing cuts are a popular coping strategy. "A number of companies are trying to find ways to offset the medtech tax," Ms Wuensch says. "Stryker started last fall talking about managing SG&A to hurdle the medtech tax, and Zimmer has discussed it in that manner."

Most companies are trying to mitigate the tax in the first year, Ms Wuensch says. There could be more cuts to SG&A, share repurchase cancellations, greater effort to manage tax rates, and attempts by companies to pass some of the hit on to buyers.

Lead failures

As well as a buffeting by economic winds, St Jude has suffered more specific problems. Its Riata leads, used to connect an implantable cardioverter defibrillator (ICD) or cardiac resynchronisation therapy defibrillator (CRT-D) to cardiac tissue in order to monitor a patient's heart rate and regulate it by delivering electric shocks, was recalled by the FDA last November. The lead insulation had been found prone to abrasion, and in some cases pacing therapy was not delivered as intended. Two patient deaths and one serious injury had been linked to the leads' failure, and they have been implicated in a further 20 deaths.

This nightmare is now recurring. The Durata leads, replacements for the Riata series, appear to have the same flaws. A search of the US the Manufacturers and User Facility Device Experience database yielded 52 reports of failing Durata leads. Three of these were ascribed to failures of the Optim insulation coating used on the wires. The FDA has insisted that St Jude conduct a three-year study of all its leads.

Ms Wuensch says that these travails have not affected St Jude as badly as may have been expected: in the second quarter of 2012, BMO estimated that St Jude Medical's share of the ICD market actually increased, despite the recall. US launch of a world-first quadripolar pacing lead in 2011, will have aided St Jude here. Analysts at Bank of America Merrill Lynch, however, said that there was "continued uncertainty" around the ICD share.

New products

As is appropriate for a firm named after the patron saint of lost causes, St Jude seems to be bouncing back. New products that have either launched recently or will reach market soon include technologies for renal denervation and fractional flow reserve and a transcatheter heart valve.

Renal denervation, a technique to treat hypertension by burning through the nerves surrounding the renal arteries from within the blood vessels, using electrodes on a wire inserted through the vasculature, is arguably the hottest thing in interventional cardiology. Medtronic's Symplicity device was first to hit Europe, gaining CE mark in 2008, but St Jude's EnligHTN followed it in May this year. EnligHTN has four electrodes where Symplicity has just one, and St Jude claims that this allows a faster and more reliable ablation procedure, which could see it take significant share from the leader. Three other companies have renal denervation technology on the European market – ReCor Medical, Vessix Vascular and Cardiosonic – but these are relative minnows.

The other white-hot innovation area is transcatheter heart valves. Currently, Edwards Lifesciences has cornered the US market, but Europe is more welcoming; plenty of companies are planning to break in, and St Jude is one of them. Its transcatheter aortic valve implantation (TAVI) product, called Portico, is set for CE mark later this year. Initial sales will be modest, but ought to increase steadily throughout 2013.

The worldwide market for TAVI devices will reach $1bn next year and St Jude will be the fifth company to reach Europe, following Edwards and Medtronic and niche TAVI specialists JenaValve and Symetis.

Imaging

The St Paul, Minnesota company is also contesting the $200m fractional flow reserve (FFR) market with its Ilumien system, the first to combine FFR and optical coherence tomography (OCT). Both are vascular imaging techniques: FFR identifies narrowings in the coronary vasculature that can cause cardiac ischaemia, and is used to direct coronary interventions. OCT uses near-infrared light to image blood vessels, and is often used to guide stent placement.

Until the European launch of Ilumien in July 2011, St Jude was at a competitive disadvantage to rival company Volcano which offered a platform combining FFR and intravascular ultrasound, another imaging modality. Since then, Ilumien has helped St. Jude Medical win share, and the company says that it has converted over 15% of the IVUS market to OCT. Ilumien gained US approval in late 2011.

However, St Jude has been mired in litigation with Volcano since 2010, with St Jude accusing Volcano of infringing its patent on the PressureWire FFR device with its PrimeWire system; Volcano claims the reverse. It is hard to predict the outcome of this dispute, though it is worth noting that Volcano is a smaller, more specialised firm and relies on its FFR tech to a greater degree than St Jude, and its shares are trading high – Volcano's investors are obviously keeping faith.

Future

St Jude has as wide-ranging technology base which also encompasses MRI-compatible pacemaker devices, products for closing holes in the heart and neuromodulation technology for Parkinson's and other diseases. This will shield it from relatively minor setbacks such as a potential loss in a patent case as well as the seismic economic changes throughout the medtech sector.

"In the near term we're sort of living quarter by quarter, both on the ICD numbers and to make sure that there are no larger problems with Durata," Ms Wuensch says, adding that it will take time for the new technologies to have an effect on the firm's bottom line. St Jude Medical could have a bright future, but for that to come about, she says, "people need to get either comfortable that Durata is not going to come back and bite them or get comfortable about the new product pipeline."

To contact the writer of this story email Elizabeth Cairns in London at elizabethc@epvantage.com