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Cardio-Neuro Innovator LivaNova Prepares For Challenges Ahead

by [Ashley Yeo](#)

LivaNova was formed from the merger of cardiovascular disease therapy company Sorin Group and neuromodulation innovator Cyberonics. The role and place in the industry of this new mega group might not be obvious to all, but incoming CEO Damien McDonald already has a vision of creating a disciplined company that leverages synergies and gets closer to the customer base.

- Bringing two major and ostensibly discrete high-risk businesses in cardio and neuro together under one roof was a fascinating concept when new company LivaNova unveiled plans in 2015 to do just that, and derive synergies while opening up new innovation channels.
- A year into the merger, LivaNova elevated ex-Danaher corporate vice president Damien McDonald to the global CEO role on a faster-than-expected trajectory. He is tasked with convincing the market about the group's technologies and a market approach that relies on regional strengths, and all this at a time when health systems are ramping up their demands on manufacturers.
- As well as adjusting for a new group structure, LivaNova shareholders have had to factor in market changes in hospital buying patterns, regulatory headwinds and a 2016 re-guide on sales, against a backdrop of industry restructuring and a focus on new types of provider partnerships that will shape the future of medtech businesses.

"Quite sudden" and "a bit humbling." These are just some of the words that incoming [LivaNova PLC](#) CEO Damien McDonald uses to describe his rapid elevation to the position of head of the group – and on this particular occasion he was addressing investors at the *Jefferies Global Healthcare Conference* in London last November, ahead of his official installation as CEO on January 1, 2017.

McDonald had been drafted in from [DanaHER Corp.](#) as chief operating officer of the NASDAQ-

listed company in early October 2016 (LivaNova cancelled its London listing with effect from April 4, 2017, citing low trading volumes there). But just a month later, on November 2, 2016, his succession as LivaNova CEO was unveiled. At the same time, the incumbent André-Michel Ballester's retirement at the end of 2016 was announced.

Ballester had been the CEO of [Sorin Group SPA](#) from 2007 to 2015, and of LivaNova thereafter. "André-Michel has done a great job in getting the company to where it is, and the board simply decided that now is the time to transition," McDonald told investors at the Jefferies session. (Also see "[Value-Based Medtech Rides The Money-Go-Round Into 2016](#)" - In Vivo, 25 Jan, 2016.)

Committed To Steering A New Course At LivaNova

The job of delivering on new organizational and business implementation models is now McDonald's principally. But it is a task he has rapidly bought into, bearing in mind that the merger and the subsequent identification of the business' new priorities pre-dated his arrival at LivaNova.

"No one is satisfied by the numbers," McDonald made clear in comments that followed the third-quarter 2016 sales dip of 0.4% (constant currency) in cardiac surgery (cardiopulmonary devices and heart valves), LivaNova's largest product sector. CRM and neuromodulation had third-quarter mid-single-digit increases; however, the overall 2.4% constant currency growth was below LivaNova's expectations for the quarter.

But McDonald was equally clear on the potential. Sharing the Jefferies stage with LivaNova chief financial officer Vivid Sehgal, McDonald stressed, "The building blocks of the company are solid."

Full-year 2016 sales released on March 1, 2017, showed net sales flat (+1% in constant currency) at \$1.214 billion, with only neuromodulation showing any growth (+8.8% in constant currency), due mainly to the adoption and growth of *AspireSR* in drug-resistant epilepsy.

But other full-year 2016 elements were more encouraging. McDonald was able to announce that

LivaNova – A Merger Of Equals

LivaNova was formed in 2015 from the combining of Sorin Group SPA and Cyberonics Inc. [\[See Deal\]](#) Merger arrangements had commenced in February 2015 and shares in the new company were listed in both the US and London on October 19, 2015. A new group structure of three business units emerged: neuromodulation (Cyberonics' legacy business), cardiac rhythm management (CRM) and cardiac surgery (both ex-Sorin businesses). Their operating HQs are in Houston, TX; Clamart, France; and Mirandola, Italy, respectively. LivaNova also has a new ventures division, and the group's registered office is in London, UK.

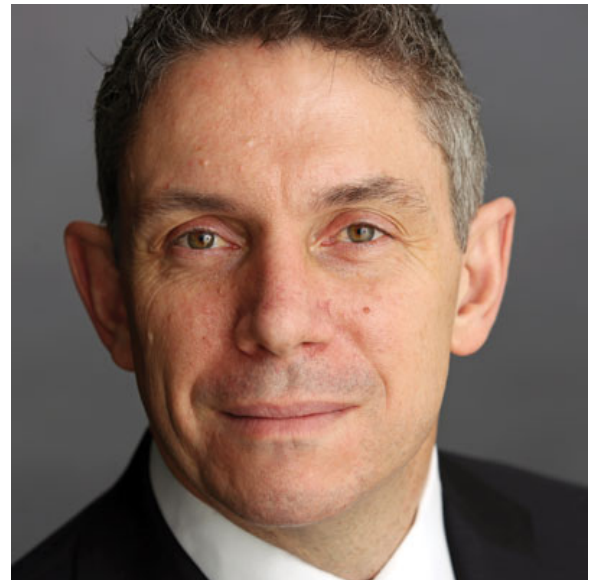
LivaNova ended the year with an adjusted gross margin of 64.6% – 150 bps higher than in 2015; met its \$19 million synergies target for 2016; reduced its effective tax rates; improved inventory channels; enhanced distributor relationships; and signed off 2016 with adjusted EPS of \$3.05 – "which was at the high end of guidance."

Even though the company was not able to grow the top line as much as it would have liked, for McDonald, the general performance bore out his fall 2016 assertions that LivaNova was making headway with "a great business that has tremendous products, just launched and in the pipeline." His enthusiasm was bolstered by assertions that the group has "a lot of runway on margin, is profitable, has a great balance sheet and some great equity investments that have some near-term opportunities."

The Ground Game

Encouraging to hear. But in spite of the good news on gross margin, the company knows it has work to do. The CEO wants more discipline around how LivaNova runs its SG&A profile and its R&D. He also wants more discipline about how it drives sales: the group's recent re-organization resulted in the adoption of a geographic sales structure, which aims to get closer to customers.

McDonald, Australian by birth but having spent the past 15 years in the US corporate world, borrows an expression that his ex-Danaher, [Zimmer Biomet Holdings Inc.](#) and [Johnson & Johnson](#) colleagues in the US would be familiar with: "We've just got to get our ground game going."



Damien McDonald

The legacy from Danaher, where McDonald led the \$1.5 billion dental consumables division, will be a focus on execution. He is counting on bringing this discipline to operational performance and ingraining this into his new colleagues' approaches to business.

And just a few short weeks after accepting the chief operating officer role, he was able to report that the "embers of lean manufacturing" were already present in some LivaNova operations in Europe. He was seeing continuous improvement actions that he has espoused (*see box*), like the squeezing of development times, lean manufacturing, a reinvigoration of the portfolio and optimization of speed to market. "These are all good developments, and we want them to accelerate," he said.

To those who might question the wisdom of bringing two ostensibly diverse companies together,

McDonald is uncompromising: "I still believe this was the right thing to do. There are signs that the geographies reorganization will bring us closer to customers, and we are already seeing in the US how that is changing our conversations," he said at the March 1 results announcement. The implication is that by themselves, Cyberonics Inc. and Sorin would have found this more difficult to achieve.

"We're a year in – and we see big opportunities. The customer-centric side will read through. And on the technology side, we also see huge opportunities from neuromodulation and CRM coming together – ideas like smaller implantable devices to treat chronic disease, and bringing those technologies to market faster."

But drill down further, and some might question LivaNova's ability to compete in CRM. It is an interesting market, but observers will wonder what is the strategy for competing with the likes of global heavyweights [*St. Jude Medical Inc./Abbott Laboratories Inc.*](#), [*Boston Scientific Corp.*](#) and [*Medtronic PLC.*](#)

"We've made a decision to be regional not global. This is a really important decision and allows for better attention for customers," McDonald says. The rationale is that the relationships are much stronger, but so too is LivaNova's spread of unique technologies. These include the heart failure technology *SonR*, which uses a contractility sensor embedded in the tip of a *SonRtip* – a "fundamentally different" technology that provides heart failure patients with automatic and frequent AV and VV CRT optimization at rest and during exercise.

So instead of tackling "the whole \$9 billion," LivaNova plans to focus on those areas where it has successful footprints – markets such as Japan and France, for instance. "We believe we can make a difference with these technologies, and we will continue to be patient-centric," asserts McDonald.

Geographic Reorganization

The recent business reviews led to a de-emphasis of some technologies in some geographies. For example, LivaNova has deprioritized CRM in the US and is investing to support activities in emerging markets. The company has been reallocating money away from what it perceives as lower growth areas, and is not cutting to a position that hinders long-term growth, says LivaNova's Sehgal.

Continuous Improvement Comes To LivaNova

The concepts of continuous improvement and lean manufacturing are generic; in McDonald's previous post, they were defined as "driving a never-ending cycle of change and improvement, focusing on exceptional people developing outstanding plans and executing

At the end of 2015, the firm identified emerging markets as accounting for 14% of its growth, prompting further efforts to strengthen its presence and develop a pathway to growth, especially in China.

McDonald notes that bringing the two companies together has given LivaNova the ability to be more flexible. The CEO observes that Cyberonics *was* investing, but did not have the balance sheet and P&L strength that LivaNova does as a combined company.

them using world-class tools to construct sustainable processes, resulting in superior performance." This platform then attracts exceptional people, who continue the cycle, guided by a simple philosophy rooted in the customer-facing priorities of quality, delivery, cost and innovation.

More Potential In Neuromodulation

LivaNova says it has increased spending in neuromodulation, and has been studying just how clinics work in the space, identifying opportunities to invest in customer-facing elements where LivaNova believes it can make a difference. "This is a patient-by-patient play and we've not been able to do work in the big clinics in the way that a combined entity could do," says McDonald.

Equally, the company will continue to invest in clinical trials, with McDonald pointing to a stack of evidence showing that *Vagus Nerve Stimulation (VNS) Therapy* in epilepsy makes a difference. Nevertheless, there is still a lot of room in epilepsy: of the 1 million drug-resistant epileptics in the US, only about 5,000 have received VNS Therapy.

LivaNova has also recently begun a European initiative to develop the market for VNS Therapy in depression. Its findings will provide a lot of learning for the rest of the group worldwide. There is no precise timing available for this project, but the group sees depression as representing a major long-term opportunity for its VNS Therapy in the US, where it is still subject to a non-coverage decision from CMS.

Of LivaNova's neuromodulation business, 80% is in the US and just 20% is in RoW. The US focus is due to the "huge amount of patient pathway" here. But there are longer-term ambitions to grow the business outside the US; for instance, a sales force has been set up in Canada for both CRM and neuromodulation.

Full-year 2016 neuromodulation sales (\$351.4 million) rose by 8.8% due largely to increased adoption of AspireSR, and average new patient growth in 2016 was roughly 7% for the device.

McDonald is energized by the general product mix and new product plans at LivaNova. He tells *In Vivo*, "We have a strong product mix with some key growth drivers in *Perceval*, *Inspire*, *Platinum* and *AspireSR*. We also operate as the market leader in a number of areas, notably with our heart-

lung machine, oxygenator, epilepsy device and dual-chamber pacemaker.” LivaNova allocates 10% of sales to R&D.

The CEO adds, "The team has done a great job of rearranging the pipeline. We're looking to launch a product every 18 to 24 months – it's a new 'cadence' and more patient centric." His priorities include maximizing the data from devices as the company continues to innovate.

"The team has done a great job of rearranging the pipeline. We're looking to launch a product every 18 to 24 months." – Damien McDonald

And McDonald clearly sees opportunities around the mitral valve space: "We've made early investments and are now seeing the opportunities read through."

2016 Re-guide After Sales Headwinds

But 2016 overall sales guidance was cut in the fall after three fundamental sales shifts in cardiopulmonary (CP) and CRM.

- A new sales trajectory is being seen in heart-lung machines in Europe due to a change in hospital buying patterns. LivaNova holds some 70% of the global market (and a higher share in Europe) – and stresses it has not lost share, but acknowledges that the buying change was a surprise. The softness in capital equipment sales is rather Euro-centric. In Europe, new purchases are being put on hold and providers are retaining equipment for longer in anticipation of the next round of innovation. That is not the case for LivaNova in the US, where 2016 heart-lung machine sales (excluding heater cooler devices – see below) were comparable to 2015.
- The second was around the *3T Heater-Cooler* following a warning letter sent out in early 2016 over bacterial contamination issues. LivaNova has taken remedial action and is working with the FDA. It is setting aside some \$38 million (including costs already incurred) to: offer a "loaner program" to customers who have seen contamination in machines manufactured before September 2014 – this program started in the US in fourth-quarter 2016; offer a deep disinfection service; and address a design change – which will happen in Europe as of second-quarter 2017. It is assumed that all devices currently in use will receive the design solution in 2017 and 2018. But there has been a softness in global sales as of October 2016, and there is a supposition that global sales of this segment will represent under 1% of

LivaNova worldwide sales in 2017.

- The third was an unexpected delay in European approval of the *IS4 Platinum CRT-D* devices, dedicated to the use of quadripolar left ventricular leads with IS4 compatibilities, which caused some inflexion in sales growth. LivaNova's overall CRM sales in 2016 totaled \$249.1 million, down by 4.7% in constant currency due partly to customer transitioning from *Kora 100* to *Kora 250*, said by LivaNova to be the world's smallest full-body MRI conditional pacemaker.

Within cardiac surgery (sales of \$611.7 million in 2016) – the one area where LivaNova claims a true global presence – CP represents almost 80% of cardiac surgery revenues (\$474.4 million in 2016). The largest contributor is the oxygenator business – a segment where LivaNova holds a 30% share globally. Inspire, its newest oxygenator, did well over the full year.

The other element of cardiac surgery is the heart valve business (\$137.3 million in 2016). LivaNova has guided to \$80 million to \$100 million global sales of its Perceval transcatheter valve by 2018. Transcatheter valves are starting to penetrate the current surgical valve market. McDonald feels that Perceval's sales are on track, and is happy that part of the sales strategy for LivaNova is to target US hospitals that are not currently using Perceval equivalents.

Factors At Play For 2017 Guidance

LivaNova's net sales on a constant currency basis are targeted to grow by 1% to 3% in 2017, with adjusted operating income in the high teens.

These assumptions factor in the launch of the next-generation VNS Therapy device, *SenTiva* (combining the small size of *Demi Pulse* with the advanced technology of *AspireSR*). McDonald is enthusiastic about the new offering, telling *In Vivo*, “We plan to launch SenTiva in the second half of 2017, creating a significant addition to our neuromodulation portfolio and allowing us to provide epilepsy patients with the latest technology in a very small device.”

This outlook also assumes that Perceval continues to drive strong US and European growth in the cardiac surgery segment, *Kora 250* continues to gain share in Japan within the CRM segment, benefits come through from the IS4 standard launch in Europe, and tissue valve sales offset the continued softness in mechanical valves.

McDonald entered 2017 as LivaNova CEO in the knowledge that, in his own words, 2016 “had more moving pieces than originally expected.” Despite the headwinds, he was nonetheless encouraged by LivaNova's first full year. Its second will be interesting to watch unfold.