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LivaNova On The Mend With Stronger, Sharper Focus

by [Tina Tan](#)

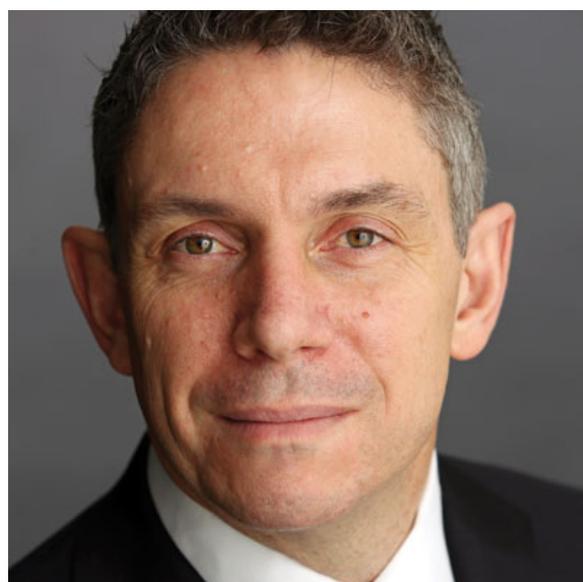
LivaNova has had a reboot and its new senior management team, including a new CEO, looks to be steering the \$1.2bn cardio-neuro group towards growth. A more stringent focus on the cardiac surgery and neuromodulation businesses – boosted by strategic M&A tuck-ins – are expected to reap short-term wins, while calculated bets on multiple shots on goal will hopefully bring longer-term rewards. As he approaches his one-year anniversary at LivaNova, CEO Damien McDonald chats to *Medtech Insight* about his journey so far to unlocking the significant potential he believes the company holds.

Damien McDonald likes fixing things and [LivaNova PLC](#), it would be fair to say, was a fixer-upper when he joined the group nearly a year ago.

LivaNova was formed in 2015 following the merger of Sorin and Cyberonics, two companies with a collective history of nearly 90 years and both leaders in their respective fields of cardiovascular disease therapy and vagus nerve stimulation. While some questioned the rationale of combining two seemingly disparate businesses, supporters of the deal maintained that the merged entity would have the scale to push a broader product offering deeper into the market, and thus accelerate top-line growth, drive synergies and open new avenues for innovation. However, revenue growth post-merger proved slow. Total sales from LivaNova's three key businesses – cardiac surgery, neuromodulation and cardiac rhythm management (CRM) – barely increased by 1% in the first two quarters of 2016. While Q3 2016 saw a slight improvement of 3% growth, revenue took a big tumble in the final quarter, declining 2.3%. The particularly weak fourth quarter led to 2016 revenue being almost flat for LivaNova's first full fiscal year, increasing just 0.8% from the previous year to \$1.22bn. The promised synergies also didn't materialize in LivaNova's 2016 income statement, with an operating margin of 18%, significantly lower than its medtech peers.

It was in this context that McDonald came to LivaNova. He joined the company as COO in October 2016, and only a month later – "a little quicker than I expected," he admits – was named successor to outgoing CEO (and former Sorin head) André-Michel Ballester. Some two weeks after the CEO-transition was announced in November, McDonald was speaking at the Jefferies Global Health Care Conference, where he maintained that the Sorin-Cyberonics merger was "still the right thing to do", offering "geographic synergies and a more customer-centric focus," among other things. LivaNova's building blocks, McDonald reassured investors at the meeting, were "very solid" and there was a lot of runway for more substantial growth. (Also see "[IEFHCLON16: Growth Strategies And What's In Store Post-US Election](#)" - Medtech Insight, 17 Nov, 2016.).

This belief in LivaNova's potential has not proved groundless and, today, since McDonald officially took the helm on Jan. 1, LivaNova seems to be on the mend. The company's top-line growth this year to date has been modest but at least it is moving in the right direction. The first quarter of 2017 reported a slight year-over-year revenue decline of 0.7%, at \$285.1m, but this improved in the second quarter to a 0.1% revenue increase, at \$321.4m. The third quarter – the results of which the company will announce on Nov 2 – is expected to see a more substantial jump. Based on the average estimate of five analysts covering the company's stock, LivaNova is forecast to report Q3 revenue in the range of \$295.4m-300.48m, a 1.8% growth, year-over-year. Others have an even more optimistic outlook, like Jefferies analyst Raj Denhoy, who forecast revenue growth of 2.3% for Q3 and further improvement into Q4 at a predicted growth of 2.5%. Indeed, Denhoy's calculations project a continued upward trajectory for LivaNova in the coming years: "We model [annual] sales growth improving to around 4% by 2020, from the current 0.8%," he wrote in a Sept.8 research note.



McDonald set out four strategic pillars to support LivaNova's transformation: growth, profitability, talent, culture.

Source: Source: LivaNova PLC

McDonald attributes this achievement to having "a team that is passionate about fixing something that has so much promise." "The opportunity [at LivaNova] is really tremendous in terms of the three or four major disease states where we have competitive advantages but were not being exploited," he tells *Medtech Insight* in an interview during the company's London investor meeting on Sept 20.

Unlocking opportunities and accelerating growth in billion-dollar businesses – large organizations that run the risk of being too unwieldy – is something McDonald knows a thing or

two about. He had cut his teeth at diversified health care group Johnson & Johnson, where he worked across the different medical device franchises, including leading the marketing for Ethicon, a \$2bn-plus company. Just before he joined LivaNova, he was group executive and corporate vice-president at Danaher; there, he led the \$1.4bn-group of dental consumables businesses.

"I was lucky enough to be exposed to these various operating systems and industry leaders who, for various reasons, have been successful and one of the great things I have been able to do is bring the best bits of what I know into this role [at LivaNova]. So, J&J, I really believed, had tremendous strategy. Danaher was great at executing. Those companies each provided a different learning opportunity for me," says McDonald.

And it's people with such similar broad experiences – of portfolio management, accelerating growth and driving revenue while streamlining operations to improve margins – that McDonald has brought into the organization. For example, among the new faces in LivaNova's senior management team is Thad Huston, who stepped into the role of CFO in May. Huston spent over 25 years at J&J and was most recently CFO of the group's medical devices division. Then there is Alistair Simpson, who joined LivaNova in April to oversee the company's biggest division, cardiac surgery. Simpson's background overlaps that of McDonald and Huston, having come from one of Danaher's dental consumables subsidiary, Kerr, and is part of the J&J alumni.

LivaNova's new senior executives are charged with executing the four strategic pillars McDonald had set out for the company: growth, profitability, talent and culture.

"These four pillars all hang together. It was very clear to me that we were growing, but just not fast enough; we were profitable, but there was no focus on really driving that profitability. The talent was definitely there, but needed to be unlocked and enhanced. And culturally, [at LivaNova], there wasn't the mentality of needing to continuously improve, needing to be accountable and there certainly wasn't a sense of teamwork, right from the top down," says McDonald.

LivaNova was and still is essentially a "head and heart" company, but it does not want to be everything to everyone, McDonald asserts.

These strategic pillars will bring that all-important focus underpinning LivaNova's transformation. This focus needed to be strong and clear to support the LivaNova story – what the company is about and what its goals are – and get buy-in from its stakeholders, not just its customers or its investors who might have lingering reservations about the Sorin-Cyberonics merger, but also the people working in the organization.

"When I came to LivaNova, it wasn't clear what we wanted to be. As I went around the company and talked to people, asking them 'what do we want LivaNova to be, how do we get there, what do you need me to do, how can I contribute', these things were not easy for people to see," says McDonald. "That's why we talk about the four strategic pillars that we need to focus on. If you can't map your activity back to these four pillars somehow, then either we haven't helped you understand your job or you are doing things in your job that are not helping the story line. That clarity made an incredible difference."

Sharpened Focus

So what exactly is LivaNova about? How has its story line changed in the last year? LivaNova was and still is essentially a "head and heart" company, but it does not want to be everything to everyone, McDonald asserts. Its focus is now sharpened on legacy areas of strength and market leadership, which, it has been determined, does not include cardiac rhythm management.

LivaNova announced Sept. 14 that it was exploring strategic options for CRM, the smallest of the three business groups (accounting for 20% of H1 2017 revenue). CRM sales declined 4% in 2016, as the business – which has about 2-3% of global market share, according to Jefferies' figures – struggled to compete in a space dominated by heavyweights like Medtronic, Abbott and Boston Scientific. But it did have strengths in certain geographies and "a great pipeline", McDonald told attendees of the Sept 20 London investor meeting – CRM just no longer fits strategically in LivaNova's portfolio and its long-term growth plans. "This is a \$250m-ish business, with good strengths in Europe and Japan, and has interesting science and tech to back it," he said, adding that there was potential for good growth opportunity if it went to someone who could give the CRM business the required attention and funding. "If it weren't for the other parts of [LivaNova's] business, I'd keep and fix [CRM] as I like fixing things. But it isn't the right portfolio fit," the CEO maintained.

This leaves LivaNova to further nurture and build on cardiac surgery, where Sorin's legacy S5 heart-lung machine has been a market leader for 40 years, and neuromodulation, where Cyberonics was a pioneer of VNS therapy, especially in epilepsy.

While LivaNova already has market leadership positions in these two areas, there is still plenty of room for growth. Customer visibility is now a critical component in LivaNova's tactics to ensure its leading products do not lose share to competitors, as well as to drive demand and grow sales for its other offerings. For example, in the cardiopulmonary business, LivaNova has a 70% share

of the heart-lung machine (HLM) market, with its S5 system. By introducing a database of its HLM customers, with information on where the customers are, the age of the HLMs they have, when the systems are reaching the end of their life cycle, LivaNova's sales team can use this data to identify their targets more effectively. Additionally, increased customer visibility enables the sales team to better leverage LivaNova's HLM footprint to boost sales of the company's oxygenators (an important component of HLMs) and address the discrepancy in market share of these two products (LivaNova only has 30% oxygenator market share).

The source for LivaNova's other significant near-term growth opportunities within its existing portfolio is multi-directional. This includes, among other things:

- A recent US CMS approval for a new technology add-on payment code on its *Perceval* minimally invasive aortic valve, the only sutureless heart valve on the market. This NTAP code means CMS will now reimburse hospitals up to an additional \$6,000-plus for *Perceval* procedures, which would help drive penetration of the device in the US market and boost its current 20% global market share; and
- The expanded US approval of the implantable VNS system to cover use of the therapy in pediatric epilepsy patients as young as four years old. As epilepsy is often diagnosed at a young age, allowing treatment with VNS in pediatric patients should yield better results, further strengthen the clinical evidence supporting the use of this therapy and ultimately boost adoption, which still remains very low (there are three million epilepsy patients in the US, of which one million have drug-resistant epilepsy and are possible VNS candidates. To date, LivaNova has implanted its *VNS Therapy System* in around 100,000 patients worldwide.)

LivaNova's Shots On Goal

During the London investor meeting, LivaNova outlined three strategic portfolio initiatives that are expected to drive growth in the longer term:

1. **VNS for treatment-resistant depression:** TRD is a bit of sensitive area as Cyberonics had unsuccessfully sought US reimbursement for this indication not just once but twice, in 2007, then in 2013. LivaNova is still betting on the TRD market for VNS, but it is now focusing its efforts in the EU. It has started a pilot trial in Germany, where there is a favorable reimbursement environment for VNS-TRD, and LivaNova is planning a scaled launch in other European countries where the company already has approval and reimbursement for this indication. It is still in dialogue with the CMS with the hope of getting that all-important thumbs up for the US market.
2. **Transcatheter mitral valve replacement:** LivaNova first invested in Caisson

M&A Tuck-Ins

But growth won't just come organically. LivaNova is actively looking for tuck-in acquisitions. The company already made an acquisition in May this year, buying Caisson International, whose clinical-stage transcatheter mitral valve replacement device is one of LivaNova's longer-term shots on goal (See box, "LivaNova's Shots On Goals").

McDonald underlined that the company will be taking a "very disciplined" approach to its M&A activity, and – similar to the Caisson transaction – it would be about bolting on LivaNova's head-and-heart remit. McDonald tells *Medtech Insight* that the firm has a very active funnel and, so far, he has been very encouraged by the opportunities. However, by taking a very disciplined view on each candidate's internal rate of return, the company has already walked away from a couple of deals "as it wasn't in the window that we liked. "People would have loved the assets, but I think they would have questioned our legitimacy if we paid those prices," he says. Elaborating more on the type of technologies that would appeal, the CEO says it has to be something that "surrounds a disease state or a call point." "I don't want to be selling a widget for the sake of selling a widget. I'm looking for things to tuck into our growth strategies."

These acquisitions will hopefully give LivaNova that additional boost to its growth trajectory over the next three years and beyond 2021, the company expects these acquired businesses to start

International in 2012 and in May this year, it bought the company outright, thus bringing in-house the Caisson TMVR technology. Currently, only Abbott's *MitraClip* is available on the market for TMVR, but other cardiology giants – Medtronic, Abbott, Edwards Lifesciences – are racing to bring to market their respective technologies. Caisson's TMVR is said to be the only TMVR system designed to be delivered through a single venous access, and implanted using a trans-septal approach. The system comprises a proprietary delivery system as well two-part, anchor-and-valve implant. LivaNova just initiated the INTERLUDE study and enrolled its first patient in Canada in August. The results from this study will be used to support CE-marking, which the company expects to obtain in 2019.

3. VNS for heart failure: Probably the longest shot out of the three strategic portfolio initiatives. The company would not be the first to explore the use of VNS for this indication, and clinical evidence of its effectiveness has been mixed. However, CEO Damien McDonald said the company "knows it works" and that LivaNova – with its combined expertise in both vagus nerve stimulation and cardiology – has the advantage of "a real understanding of the clinical pathway" involved. Having looked at other VNS-HF studies that have failed, the CEO said at the London investor meeting that he believes LivaNova can overcome the issues that led

driving incremental growth.

So, has LivaNova really picked itself up and turned the corner?

McDonald diplomatically replies that "it's way too early to declare victory."

However, change – for the better – has happened and this is just the beginning,

he believes. "If we look at our growth in the last two quarters, you'll see a slight change in the growth profile. We've started changing our profit profile – our gross margin and adjusted operating income. Culturally, we've begun the journey well and certainly in terms of market valuation, what we've seen in the last few months is people being very receptive to our story," he says. "On multiple levels, we are seeing the embers of the journey I want the company to take."

to those studies' failure. In its ongoing trial of VNS for heart failure, the firm already has "very powerful" results from the first 60 patients. "We're in a really good spot here," McDonald assured.

From the editors of Clinica