MEDTECH INSIGHT
CITELINE COMMERCIAL

06 Oct 2017 | **News**

Hindsight 20/20: Jon H. Hoem

by Tina Tan

Hindsight 20/20 is a Q&A feature where medtech industry veterans share their long experience taking diverse businesses – be they start-ups or publicly-listed entities – from strength to strength and navigating through times of crises. In this installment, Jon H. Hoem, whose career in the cardiology sector spans more than two decades, explains how his thinking on building a robust clinical strategy has changed; why he believes you should never skimp on hiring talent; and advises on the difficult patches start-ups might hit and how to navigate around them, among other topics.

Jon H. Hoem is all heart – well, almost. During the near-30 years he has worked in the medtech industry, based largely in Europe, over two thirds of this time was spent dealing with cardiovascular technologies. Hoem cut his teeth in the early 1990s in product development at ultrasound specialist *Vingmed Sound AS* (later to be acquired by GE), then moved on to various senior commercial roles in MediStim Inc., developer of ultrasound imaging systems used in cardiac surgery, then atrial fibrillation treatment company *AtriCure Inc.*

Since 2008, Hoem has been leading start-ups like *Miracor Medical Systems GMBH*, which has developed a therapy to improve outcomes of percutaneous coronary intervention in heart attack patients; *Ablative Solutions Inc.*, which is developing a renal denervation system; and currently, *CorFlow Therapeutics AG*, an early-stage start-up he cofounded in August 2016 that is also developing a technology for improving cardiac revascularization outcomes in heart attack sufferers.

Q **Medtech Insight: Much of your experience is with companies developing and commercializing high-risk, class III technologies. What is the most valuable lesson you learnt in terms of planning a robust clinical strategy for these types of devices?**

A Jon Hoem: Initially, my thinking on clinical trial design had been to take carefully planned steps, starting with the traditional small single-center safety trial, then moving on to a larger multi-center clinical trial and then finally a multi-center randomized clinical trial for efficacy. However, this approach takes too long a time and does not create meaningful evidence compared to standard of care. I've found that with this traditional approach, start-ups establish too late the comparisons between their technology and standard of care and are unable to establish evidence of improved outcomes. This, in turn, means they also arrive too late at the all-important reimbursement discussion.

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Source: Jon H. Hoem

Now, my thinking has been influenced by the "lean start-up" movement and applying the lean philosophy to the world of class III medical devices. CorFlow is developing a disruptive technology to diagnose and potentially treat Microvascular Obstruction (MVO) in severe heart attack (STEMI) patients and around 50% of all STEMI patients have MVO. In recent clinical trials, MVO has been proven to be an independent marker of short- and long-term outcomes. In my experience, the initial technology and clinical hypotheses are always wrong, which clearly have been shown in other white-space medical device fields like renal denervation. Believing that the initial hypotheses are true without generating fundamental evidence can kill a whole emerging field with enormous opportunity losses. Since our initial hypotheses are always wrong, we embraced the lean start-up approach in CorFlow by going for a minimal, viable clinical device as our first-generation prototype. This first-generation prototype serves as a learning platform without any ambitions for regulatory approvals or market launch. The *CorFlow Controlled Flow Infusion (CoFI)* Console consists of already known components which together form a new

functionality without spending too much money. This initial approach has created a completely new understanding of our technology and coronary physiology. This new understanding in the early non-clinical phase have fundamental implications for our first-in-man clinical trial design.

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A So my current thinking on clinical trial design for a potentially disruptive technology, such as CoFI, is to conduct a larger first-in-man clinical trial which will generate clinical data on the CoFI diagnostic parameters, as well as comparing standard of care against our therapeutic approach.

Q **When financial resources are tight, especially for early-stage start-ups, what have you found to be the best way to balance the books? Which area(s) of expenditure should take priority over others?**

A Hoem: My No. 1 rule of thumb is to never save when hiring the team. I have been in situations where experienced board members and venture capitalists have rejected excellent candidates over a CHF30,000 difference between asking and offer salaries. These decisions have long-lasting implications on the performance of the company and can cause the whole project to fail. When the core management team is in place and it can focus on value creation, the company will thrive and be able to deliver on milestones that are unachievable in any other setting.
Where money could be saved would be from overall planning and execution,

especially on the product development side. CorFlow began non-clinical validation testing of its CoFI console four months after we signed off on the product specifications. Again, being willing to iterate from the initial assumptions to real solutions without seeking perfection is key to establishing early proof-of-concept. Our worst enemy in early-stage medical device development is to aim for perfection and forgetting about the fundamental hypotheses we need to prove. This is a very fluid environment which the team members need to embrace and change as we discover faults in our original thinking.

I'm also a firm believer in co-location and short communication lines between team members, especially in the early phase. Forget going virtual and long email exchanges – they just don't work for complex medical devices. Daily face-to-face interaction is a key success factor second only to the quality of the team.

Q **At what stage of the business do you see start-ups stumble over the hardest? What do you consider to be "the red zone" where companies need to navigate very cautiously?**

A Hoem: This depends on the experience of the management team. In start-ups coming out of a university setting, the first stumbling block is failing to establish a robust quality management system. I continue to be amazed how many medical device start-ups fail because they never implemented a solid QMS from day one. And what is even more amazing is that this knowledge is just a phone call away: every experienced medical device entrepreneur knows that the quality system is a key factor for protecting the investments into the company. Maybe we can blame this on the overly optimistic thinking that young teams have in the start-up phase. Or the lack of insights at the board level: I don't know how many times I have heard experienced board members tell me that "quality systems don't create value." This lack of insight will come back and bite them hard if they don't have a certified QMS in place within 8-9 months after company foundation.

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A The second red zone to look out for is failing to involve the customer at a very early stage. Preferably, this customer should be in your founding team so that the "voice of the customer" is represented when the first plans are made. The number one insight in CorFlow is that we need to develop a technology that fits the work flow of an interventional cardiologist to treat acute heart attack patients. Trying to change customer behavior is not a playing field for start-ups and we should leave that to the corporates which over decades potentially can change behavior. Robert Schwartz, the other cofounder of CorFlow, calls this "passing the 2am test": we need to develop a technology that the cathlab staff likes to use also when they really want to be in bed. Finally, we talk a lot about different risks these days: regulatory, clinical, reimbursement and financing risks. However, the number one risk in any start-up is the people and avoiding conflicts over the life-time of the company. This requires alignment of the founding team, the management team and investors. Unfortunately, egos sometime get in the way for the overall good of the company which is devastating and toxic. Therefore, avoiding conflicts and spending a lot of time in forming these teams are key success factors for any company including start-ups.

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Q **If you had to put together a dream team to help you take a disruptive, white-space targeting technology from bench to market, what attributes/skills/expertise**

3 in 30: Three quick-fire questions in 30 seconds

What do you do to help unwind from the stresses of your job?

would you be looking to recruit?

A Hoem: The two first people I hire are my R&D manager and vice-president of quality assurance/regulatory affairs. In CorFlow, we spent substantial time defining these roles with an experienced headhunter. We discussed the exact fit for the company short- and long-term. Again, I was amazed how my initial assumptions changed during this headhunter debrief. It also motivated the headhunter to find the right candidates – not the ones that fulfill only part of the profile. The focus was of course on the fundamental skill sets, but the fit must be there on the softer personal side: "What makes me as CEO tick, where do I have my strengths and blind spots?" Fully accepting these and hiring experienced people who bring new and other skills to the team creates diversity and ability to tackle the unexpected.
CorFlow is now entering the second stage of the company development where clinical trial design and execution will be in the forefront. There are many medical device

My wife, Caroline, and I have always loved nature and we are lucky to have a lot of it in Switzerland and Norway. There are few places in the world where you on the same day can ski, hike, play golf and sail. We enjoy skiing and biking a lot but the time for golf is very limited these days.

Also, Caroline gave me a curry cookbook from "The Hairy Bikers." I have enjoyed making more than 30 of their curries – sharing those meals with our friends and families have been great.

Who, outside the medtech industry, do you see as a role model and why?

I recently read Jon Meacham's biography of George H.W. Bush – the 41st US President. What impressed me was Bush senior's total unselfish dedication to his role and country in a time with a lot of uncertainty. His contributions to world peace are easy to forget as are those of his peers – Helmut Kohl and Mikhail Gorbachev.

If you weren't a medtech executive, what would have been your career Plan B?

Contrary to all the other things I do, here I don't have a Plan B: I would be a medtech executive which is my dream job.

professionals who only master part of the solution whereas in a start-up each person needs to contribute on a wide spectrum of skills – they need to be comfortable wearing many hats each day. For instance, I expect my VP Clinical to contribute on the clinical trial design, the study center selection process, the training activities, the interaction with key opinion leaders, as well as study nurses, and to deliver on a successful publication strategy. That's a pretty tall order for one individual. But these professionals do exist and will thrive in a start-up environment.

Finally, my years in the US gave me a lot of respect for the professional medical device sales representative. I met sales reps coming to the launch meetings having read all publications on the technology. And they were able to pitch the technology to KOLs the next week. Unfortunately, as an engineer I was not educated to understand the keys to sales success. I was trained to believe that every answer is correct and has two lines under it. Not so in sales - it took me more than 10 years of intense trying and failing to learn how to be successful in sales.

Q **Share with us your experience of a particular crisis that a company you were involved in has encountered. How did you ultimately overcome this crisis and if things had not worked out as expected, what would you do differently now?**

A Hoem: In one of our early first-in-man cases, we had an adverse event rupturing a coronary structure. The rupture was caused by navigating the guide sheath into location and causing the bleeding with a combination of guidewire and catheter manipulation. This came as a shock especially as we had prepared well for the first-in-man clinical trial and were convinced that our preparations were enough. Fortunately, the cardiologist was able to stop the bleeding and the patient was discharged from the hospital two days after. Analyzing what happened, it became evident that our preparations were not thorough enough as we could improve on the training and support for these cases.
New product development and technology launches carry a high-risk profile especially when we talk about class III devices. However, by proper training and education the risks can substantially be reduced and balanced to the treatment effect for the patients. With technologies that are being developed for acute clinical care,

> the support and education issues are in the forefront and how to properly address them is a constant challenge. My current thinking is that physician training has to be repeated in a simulated setting and that the first acute cases have to be performed in the day time so that all support structures are in place. Also, the devices have to be designed for usability so that the cath lab staff can use the devices without clinical application support. This approach reduces the risk profile and improves adaption substantially.
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> *From the editors of Clinica*