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Medtech Startups: The Lifeblood of an Industry

Starting a small business is challenging, to say the least, but it can be very rewarding for the entrepreneur and industry alike. We asked five startup companies to share their views on what it takes to successfully launch a company and make it last.

By: [Yvonne Klöpping](#)

Startups in the medical space play a crucial role in introducing game-changing ideas and disruptive technologies. The medical device industry needs these young firms to maintain innovation, as the competitive medical industry is moving fast. It is therefore important that established firms engage with startups regularly as technologies evolve.

However, anyone thinking about starting a business is immediately struck by the challenges—and when it comes to medical device technology, they quickly can become overwhelming. Often product-centric and focused on innovation, startups encounter numerous challenges on their way to success. Some important considerations to make when starting a business include funding and cash-flow, technical issues, staffing and—most importantly—the focus of the company. The startups featured below all agree that a strong focus, perseverance and determination are essential for a company to succeed in the competitive medical device market.

Sequana Medical AG

Founded in 2006, [Sequana Medical](#) (Zürich, Switzerland) is dedicated to improving patient quality of life through innovative fluid management technologies. Sequana developed its first therapeutic product, the ALFApump System, to manage ascites—a symptom that can occur in patients with advanced liver disease, certain cancers or congestive heart failure. “The initial idea came from a young physician who was determined to find a better way to manage his patients with refractory ascites,” says President and CEO of Sequana Medical, Noel L. Johnson. “He shared his idea with an engineer who specialised in taking ideas from concept to product and building teams to then take the product to market.”

Sequana currently employs 22 people, a number that is expected to grow to 30 by the end of 2012. And while the firm is not yet profitable, Johnson expects his startup to become cash-flow positive in 2013. “You have to make sure the company always has six months of cash runway,” he advises. “Initially, Sequana Medical founders could not find adequate funding so they funded the work

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carefully and stresses the importance of getting prototypes into preclinical and clinical testing as quickly as possible to determine “real-world” issues. “Sequana had to redesign one of its catheters after it failed to meet performance requirements in early clinical testing,” he recounts to illustrate the point. Furthermore, Johnson says not to underestimate the importance of taking the time to hire bright, hard-working people with a startup mentality. “Dealing with staff who are not team players and who lack the ability to work independently and cross-functionally can cause significant distraction,” he explains. “Sequana Medical made some poor hiring choices, which cost both time and money to correct.”



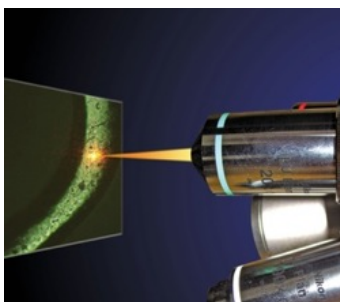
Sequana's therapeutic ALFapump System was developed to manage ascites.

Johnson's suggestions for evolving startups:

- Focus on a market where there is a critical need—the more critical, the better.
- Make sure there is a sufficient number of patients, preferably concentrated in one area or specialty.
- Understand reimbursement pathways. It is a huge advantage if there is existing reimbursement.
- Have substantial barriers in place, such as IP, distribution and speed to market, to ward off potential competitors.
- Make your product as simple and easy to use as possible.
- Watch your cash flow and always have at least six months of runway.

Nightingale-EOS Ltd

[Nightingale-EOS Ltd](#) (Wrexham, UK) is a metrology company that has developed a unique laser-based technology for measuring thin coatings and membranes, with a particular emphasis on medical implants. The company was founded by Stephen J. Morris, who spent just under 10 years in the semiconductor industry nurturing a vision of bringing that industry's storied productivity gains through the implementation of in-line quality control to the medical device sector.



“Our unique technology enables our customers to characterise and measure the thickness of single or multilayered clear coatings in the 5–200 micron range in either laboratory or in-line manufacturing environments,” says Morris. “Our objective is to make this aspect of real-time analytical technology a reality in chosen markets where this is not possible at present.”

A focused laser beam collects data to enable the measurement of small and complex-shaped samples. The technology developed by Nightingale-EOS Ltd is shown here applied to a coronary stent.

The company was incorporated in late 2005 and is now at the stage where its technology, which is packaged in its first product targeted at quality control and development laboratory applications, is available. Target applications are manufacturing processes where transparent films or membranes are applied and thickness and specification need to be efficiently controlled. “Medical device manufacturers in a number of areas are

currently talking to us and the product is being assessed,” he notes. “In the near term, the measurement of stent coatings and reinforcement membranes is likely to be our first commercial success. Applications in coatings on catheters, orthopaedic implants and other devices should follow.”

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experienced the same challenges that many other startups face,” Morris says. “We started to fundraise in late 2007, when the financial climate was pretty cold. Not being a university spin-out, and not being located in the UK’s Golden Triangle—London-Oxford-Cambridge, where many other UK technology firms are located—probably made it harder still. The fact that the source of our core technology was in the electronics industry where it was demonstrably successful, probably helped.”

Morris says it is probably too early for him to start giving advice, but here is his suggestion for evolving startups:

- Determination and perseverance are absolutely essential!

Medivation AG

Founded in 2009, [Medivation](#) (Windisch, Switzerland) provides comprehensive operating room technology development know-how and services. The firm develops complete surgical systems as well as medical devices and software. “Medivation started as a spin-off from a large orthopaedic corporation,” says CEO Jan Stifter. “The four founders were the key engineers behind a successful innovation in the field of image-guided surgery systems and have worked in this area for more than 10 years. The corporation decided to outsource this business because it wasn’t the firm’s core expertise. There was an opportunity to spin off into a separate company and continue to provide further support, while at the same time use the know how in similar markets.”

Stifter says that while Medivation developed some technologies in the area of image processing and 3-D reconstruction, which are in use today and are very advanced and probably unique, he sees the real strength of the company elsewhere. He is especially keen to adapt technologies into successful products that improve surgical outcomes and the bottom line.



Orthopaedic navigation systems from Medivation AG enable surgeons to plan, monitor and review their interventions.

Medivation started operations on 1 January 2010. It currently employs six people, one of whom is part time, and maintains a network of freelancers to help with certain aspects of a project. “We were glad to have had a project from the start and it was possible to get a few more projects in the initial stage of the company,” he notes. “Medivation was profitable from the first year onwards, which gives us more freedom to operate. But we are not a money-driven company. The founders have a long-term vision [that prioritises] relationships and networks.” The social aspect is also key, adds Stifter. “We live in a privileged part of the world and profit from the hard work of previous generations. Medivation donates 10% of its annual profits to Christian-social organisations. Last year we donated to an organisation in Peru that provides food and education to children. This gives us even more satisfaction in running our own company.”

Stifter’s suggestions for evolving startups:

- In the first phase of a startup, the most important thing is the people behind the business idea. The entrepreneurs need to have a lot of spirit, motivation and enthusiasm.
- Medivation’s biggest challenge is the constantly changing regulatory and healthcare environment. “While the regulatory hurdle to bring an innovation to market is increasing, our customers’ margins are decreasing,” says Stifter. “You need more time for a project but you have less money to develop it. This means that some innovations—even if they improve the quality of healthcare— simply do not make it to market.”

Telcare Inc.

[Telcare](#) (Bethesda, MD, USA) developed a cellular-enabled glucose meter

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members and close friends to comfort and guide them.

“The genesis of Telcare came from my experience in leading the White House policy development process for electronic medical records and health IT,” says Jonathan Javitt, CEO of Telcare Inc. “That was when we first started talking about the importance of connecting patients to the healthcare system via intelligent, remote sensors.”

Founded in 2008, Telcare began selling its monitoring system in the United States in February 2012; it will carry the CE marking by June 2012. The company, which currently employs a staff of 21, recently received the MEDTEC EMDT Innovation Award in the Best Medical Device Startup category for the development of its cellular-enabled blood glucose meter. The award was announced during MEDTEC Europe 2012 in Stuttgart, Germany.

One could assume that this device targets younger diabetes patients rather than older patients, who are not always comfortable with technology. But, says Javitt, ease of use was top of mind when designing the product and it is, in fact, very easy to use for the elderly. “There are no extra steps for the patient compared with ordinary glucose meters,” he explains. “Just put a drop of blood on the test strip, tag the data by activity (optional step), and pull the test strip. The rest is automatic.” He adds that this device is particularly valuable both for children with diabetes and for the elderly who depend on the involvement of other family members. “That’s because using Telcare’s smartphone apps, which are distributed at no charge, a family member can track every test and help keep diabetes in control.”

Javitt’s suggestion for evolving startups:

- Make sure to allow for sufficient time. For any startup, time is the greatest enemy. There is rarely room for missed steps in the R&D process or the regulatory approval process.

VirtaMed AG

Founded in October 2007, [VirtaMed](#) (Zürich, Switzerland) develops virtual reality simulators for diagnostic and therapeutic endoscopic interventions. VirtaMed currently has 14 employees with interdisciplinary backgrounds in medicine and engineering. The mission of the young company is to develop state-of-the-art endoscopic surgery training tools that achieve a high level of realism with the ultimate goal of improving the quality of patient care.

“The basic idea is to bring the concept of flight simulation into the medical world,” explains Asta Breitenmoser, VirtaMed’s Marketing Manager. “What was widely accepted as a pilot training tool is completely new in surgical training. The goal is to explore the limits of how realistically we can simulate a surgical procedure.” ETH Zürich, the Swiss Federal Institute of Technology, and other Swiss universities were part of the large research effort. “In a first step, we aimed at applying this idea to the training of hysteroscopy, which is the minimally invasive inspection and treatment of the uterine cavity,” she adds.



VirtaMed’s HystSim is a simulator for diagnostic and therapeutic hysteroscopic interventions.

“Developments in computer graphics during the last few years have enabled us to take surgical simulation to the next level,” notes Breitenmoser. “It enables ‘complication’ training such as bleeding or perforation, and the surgeon uses actual instruments from the operating room adapted for virtual reality simulation.” She adds that VirtaMed also offers custom simulators for medical device companies.

Breitenmoser’s suggestions for evolving startups:

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