Marc Julien – Co-CEO, Diabeloop, France

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12.12.2018

Tags: France, Medtech, Diabeloop, AI

Marc Julien, co-CEO of Diabeloop, presents the revolutionary "artificial pancreas" the company has developed to support type one diabetes patients. The device embeds artificial intelligence to help type one diabetics regulate their insulin intake according to their needs. He also discusses the opportunities and challenges he sees to bring such a device on the French market.

Can you please introduce the company to our international audience?

It all started in 2011 with Dr Guillaume Charpentier, at the time director of the Hôpital Sud Francilien in the south of Paris. Patients were often struggling with the complexity of controlling glycaemia on a daily basis. Dr Charpentier was looking to create a new type of technology that would lighten the heavy mental burden associated with diabetes and prevent both low blood sugar events (hypoglycemia), that are responsible for faintness and sometimes comas in the short term, and hyperglycemia, itself responsible for major complications in the long run. Indeed, several systems already existed to diffuse the insulin (insulin pumps) or to measure the glycaemia by itself, but Dr Charpentier had the idea to link both systems with an intelligent software that would make the calculations, take the decision for the patients and regulate insulin intake without the need of human intervention.

To develop the idea, he worked in partnership with one of the best technology research institutes in France, the CEA (Centre of Nuclear Studies) in Grenoble, in order to build the algorithm. The first

tests were made in silico before moving to patients' testing thanks to the funding Dr Charpentier had collected. The company Diabeloop was created in 2015 by Dr Charpentier and the today's Co-CEO Erik Huneker, following the request of the BPI (Public Investment Bank), who agreed to provide additional funding to develop the solution, providing the technology was owned by a company that they could invest in.

As a French start-up, how would you assess the support you are receiving from the government and the industry to develop your activity?

France is renowned for bringing together academics and technology institutes. They work brilliantly together, but the country is missing the investment steps to commercialize the solutions. We should learn more from the USA that, after all, was founded by immigrants who, having experienced bankruptcy in their own countries, decided to invest in the new land. This historical trait can be seen now in the way American investors do business, as they will be happy to see people who have failed and learned from their failure. The investor's mentality is also to open the capital and bring more funds to develop the business and the country later on. In France, our very state-driven and centralized system has seen the development of big companies and we tend to forget that much of real entrepreneurialism is conducted by SMEs.

However, in recent years, the BPI and the EIF (European Investment Fund) have understood the differences between the markets and are now providing tools to investors and companies to scale up these business areas. Moreover, two of their areas of focus are on the healthcare sector and the artificial intelligence segment and Diabeloop fits perfectly into these categories so we are looking forward to the future with confidence.

What have been some of the main challenges you faced in this journey of building Diabeloop from scratch?

Our first challenge was to create the right team. As we were founded in Grenoble, in the Auvergne-Rhone-Alpes region, we were able to benefit from the highly-qualified talent pool in medicine and biology that this area offers. Thanks to this team, we managed to create a first algorithm within the first year and in 2016, we ran our first clinical trials on 30 patients all across France. We used the crossover technique in the clinical trials and, to further test our system, we put our patients in three different situations: their day-to-day lives, intense exercising and special dietary regimes, so

we could see how the algorithm would adapt its responses to the most difficult scenarios. We received very promising results for these first trials which lead us to start 3-month home-clinical trials for 67 patients, using the crossover method again. The first leg was finished in September 2017 and presented significative results. It allowed us to lead a plenary session and a press presentation at the American Diabetes Association (ADA) 78th Scientific Sessions in Florida, and hence present our results to the healthcare community. The initial stage helped us start the process to attain CE certification. We were awarded it 3.5 years after the initial establishment of the company which was an achievement for the team as it is maybe the first time a therapeutic artificial intelligence device received the CE mark. We recently finished the second arm of trials and the results should be out in 2019.

Funding represents our second biggest challenge. Indeed, the French MedTech start-ups, in general, risk encountering dual Valleys of Death. The first one is during the first development of a technology until its market commercialization. It requires important funding as companies need to support the team that is developing the technologies as well as finance the material resources that they require to advance further. Some start-ups can, at least, count on the financial support of the BPI.

The second valley of death comes later. As soon as a company has its products, it should be able to market them straight away to finally secure revenues. For the French medical sector, companies actually have to enter a second system, in which they have to invest in the process again and find other finances to prove the relevance of their solutions and get public payers to pay for the system. Indeed, the current system is paid by public payers. Unfortunately, this reimbursement process can take a very long time in France, while it can be conducted within six months on other markets like the USA. As you can imagine, the return of investments is also very different depending on the country, hence, the great importance for French companies in acquiring the CE mark swiftly and so as to enter the USA directly.

What can be done to accelerate the entrance to market of innovative medical devices?

Some French governmental programs have been created to support start-ups but unfortunately, these are not adapted to our company. Therefore, our team is now working on accelerating the approval process by looking at a program that would allow us to prove ourselves. One possibility would consist of the public sector giving authorisations to present the product to a limited number of patients who will be able to use the system. As we have a connected technology, Diabeloop will

be able to control the results remotely and we could later reconvene for the patient users and see how to extend the system. This would be the best system for us, but we need to show patients and the government that our system helps patients and significantly reduces the cost of diabetes treatments and complications.

For the moment, stakeholders are agreeing on the idea and supporting it. However, we don’t know when this strategy will be implemented as the framework and timelines are not fully designed yet.

There is a parallel plan to address other markets at the same time. We have four team members working on market access around the world and some foreign doctors have even been reaching out, to us to ask how they can get our technology in their country as soon as possible. First, we are targeting more northern countries and we are looking at entering the American market as well. Our next development will be to attract more funding so that we can enter new markets and continue to invest in R&D.

Several MNCs like Medtronic or Abbott are also developing a similar technology to that of Diabeloop. How can your company compete against MNCs with seemingly unlimited resources?

We differentiate ourselves by our focus on our one and only solution while multinationals are focusing on diverse technologies and treatments. All of our work is also articulated around diabetes patients, who are the real reason why we are working. We developed a system for the patients that we are improving with the help of the patient. It is a personalized system that is adapted to their physiological and lifestyle needs, and we want to make sure patients can choose the solution that is the most adapted to their individual needs. Our objective is to build a company that will provide solutions to patients and we want to raise more capital to develop cutting-edge technology for the patients.

Clinical trials are also a great asset in our industry. They are needed to receive any certifications for CE or FDA and their results are public, so it is easier to check the advancements of competitors. So far, Diabeloop believes that most of its competition is two to three years behind. We also believe that patients are loyal to a system that they have tried and trust, so our main goal is to be the first with this technology on the European market so that we can attract loyal clients that will not go to the international players. There will be an intense competition which is good for the patients and our company as well.

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