Interview: Jui-Lin Chen PhD – CEO, MiCareo, Taiwan

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24.03.2017

Tags: Taiwan, MiCareo, Biotech, Diagnostics, Innovation, Oncology, MiSelect

Jui-Lin Chen, CEO of MiCareo, provides insights into the development of MiSelect, Micareo's pioneering platform for the analysis of Circulating Tumor Cells (CTC) and other rare cells, which proudly stands as the best product available to physicians for cancer prognosis as well as the perfect companion diagnostic for drug development and efficacy evaluation. He also documents MiCareo's overarching focus on delivering pioneering solutions targeting unmet needs in rare cell processing for personalized medicine, immunotherapies, clinical diagnostics, and biomarker discovery.

Could you walk us through the main milestones of the company and explain how you became MiCareo's CEO in 2011?

A biologist by trade, I joined Taiwan Global Biofund (TGB) and YFY Biotech Management Company *[one of the oldest biotech-focused VC funds in Taiwan, e.d.]* in early 2006. This experience among the VC industry was a great learning experience for me, as I got the opportunity to closely work with dozens of biotech entrepreneurs and identify these companies' success factors in terms of drug and product development as well as growth strategies.

In addition to traditional investment activities, one of YFY Biotech Management Company's objectives was to incubate new biopharmaceutical and medical device companies, meaning that we were actively screening new technologies that would be worth developing in Taiwan. As part of this endeavor, we visited the most prestigious universities and research centers in the country, discussing with their scientists the most promising early-stage products and technology platforms

they were working on. Nevertheless, at that time, the eagerness of Taiwanese academics to bring their research projects onto a commercial stage was more limited than it is nowadays. We then started to expand our screening activities to the US, leveraging the then-recently established Stanford-Taiwan Biomedical Fellowship Program to build up connections with US-based scientists. In 2009, we met with Dr. Chiu, Professor of Chemistry, Professor of Analytical Chemistry, and Professor of Bioengineering at the University of Washington, Seattle and future co-founder of MiCareo, who introduced us to the pioneering technology he was working on.

We immediately identified the great commercial potential that Dr. Chiu's innovation could hold if it was applied to a marketable product. Furthermore, as Dr. Chiu was already working on rare cell isolation and circulating tumor cells (CTC), we then already held clinical data at hand to demonstrate the heightened outcomes brought by this technology. In the meantime, we wanted to invest in a product focused on unmet medical needs, for which no satisfactory technology had already been developed. A few years ago, liquid biopsy was just emerging and only an extremely small number of CTC-focused companies were active in the world. In this regard, we truly held a groundbreaking technology in an emerging field where only "me-too" and "me-better" products were available in the international market. Dr. Chiu's technology was then meeting all our criteria and we were ready to move forward on the licensing of the technology.

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Given the great prospect of this technology, how do you explain the fact that this technology had not drawn the attention of US-based investors?

Dr. Chiu was in contact with some US-based investors; nevertheless, considering the extremely challenging economic context in the US in the years 2008-2009, it was almost impossible to access funding for such a pioneering project. On the other hand, the economic turmoil faced by the US economy created a very favorable timing for us. We however set two conditions to our investment: first, to move the company's operations from the US to Taiwan; and, second, ensure that Dr. Chiu and Dr. Shiro, co-founders of the technology, will remain committed to MiCareo and accept to join its executive management. Closing this agreement was easier said than done, as it took me almost two years to convince the board of the University of Washington, Seattle to accept that – by licensing-out this technology – R&D activities will then be conducted in Taiwan and not in the US, while, in the meantime, I had to ensure TGB's steering committee and board would fully support our first attempt to incubate a pioneering technology in-licensed from the US.

Once you reached this important agreement, what were some of the main challenges you faced when transforming such a pioneering technology into a marketable product?

When we in-licensed the technology, it looked like a complex open system that would fill up a ground surface of around 7 square meters. Now, our product's dimensions are slightly larger than these of a microwave! As you can imagine, this translation phase was not completed overnight and it took us around four years to design, develop and start manufacturing MiSelect, our final product.

Our first challenge was to find the right people to lead the exploratory phase of our product's development. When we decided to bring the technology from the US to Taiwan, our plan was to leverage Taiwan's talent pool in electronics, optics, and precision machinery industries. Nevertheless, our country's expertise in this field mainly relates to the development of consumer products, while building a team of medical device engineers – especially when it comes to such an innovative product – turned our to be a lengthier process than expected. In the meantime, designing our product and understanding what should become its main requirements implied to work closely with clinical KOLs – another necessary but lengthy process. Overall, this development phase, which encompassed the time needed to build up MiCareo's teams and design the main specificities of our product, took us almost two and half years.

In this regard, if Taiwan really wants to become one of the most advanced countries in the medical device field, I think we still need to strengthen our country's translational capacity, including both product engineering and design.

You mentioned how you have been working with KOLs to truly build the value proposition of your product and fully leverage its technology's potential. How would you describe the added value brought by MiSelect?

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MiCareo truly stands as a technology platform company. Given the number of patents we hold, we undoubtedly are one of the most advanced companies in the CTC field globally. In the meantime, CTC are only one among many types of rare cells for which our product can truly make a difference throughout the oncology-related spectrum.

At the moment, we are particularly focused on the development of products that can facilitate immuno-oncology therapies, as MiSelect can isolate and analyze both CTC and rare immune cells. Looking at immune checkpoint inhibitors for example, there was no satisfactory tool available in the market that can precisely and efficiently identify suitable patient for treatment and monitor the

efficacy. In this regard, we then decided to position our product as a companion diagnostic for the development of immunotherapies in the oncology field.

Given MiSelect's positioning as a companion diagnostic, are you already partnering with pharmaceutical companies developing immunotherapies?

Very close to it and it truly stands as our main objective in the short and mid-term. Currently, we are already partnering with the most reputed hospitals in Taiwan, which are all involved in groundbreaking clinical trials. This local collaboration will help us to reach out to pharmaceutical companies, while – in the meantime – it provides us with the opportunity to generate the clinical data we need to approach pharmaceutical companies and demonstrate why MiSelect is the product they need to maximize the outcomes of the clinical development activities.

For example, we have a clinical trial partnership with the Chang Gung Memorial Hospital in metastatic breast cancer, for which we analyze CTC as well as PD-L1 biomarkers. Furthermore, for early stage and some internal organ cancers, it is usually impossible to conduct tissue biopsy; but with MiSelect, these hospital's physicians can now make their treatment decisions based on liquid biopsy too. We also partner with Taiwanese scientists working on checkpoint inhibitors to treat head neck cancer, while MiSelect, in addition to CTCs, can also monitor the level of various types of tumor-related immune cells in the patient's blood over the course of the treatment, providing healthcare professionals and providers with a new layer of visibility and information.

In cancer studies, there are actually three different types of liquid biopsy, depending on their targets: cell-free tumor DNA (cftDNA), circulating tumor cells (CTCs), or exosomes. Our company's overarching objective is to become the best partner of physicians and drug development companies for cell-based (i.e. CTC and tumor-related immune cells) liquid biopsy. We have already submitted two abstracts for peer-reviewed publications regarding the results of our collaboration with the aforementioned Taiwanese hospitals. Overall, we really adopt an evidence-backed, scientific-based marketing and internationalization approach to raise awareness around our product's capacity among the industry and global research community.

In terms of upcoming projects, we will direct our R&D efforts at the isolation of single rare cell and analysis of its molecular information critical to cancer treatment, such as neo-antigen analysis of CTC and TCR analysis of tumor-related immune cell. These still stand as frontier area, where a substantial R&D effort needs to be provided and only a very few number of companies beside MiCareo could be able to bring ground-breaking products targeting these unmet medical needs.

As CEO of the company, what are your main priorities to nurture the development of the company within the next few years?

Our first and foremost priority is to get regulatory approvals in all key markets, including GMP certification and medical device classification. We notably submitted in January 2017 our application for TFDA's GMP certification, which we should receive within the next four months. Once we get this certification, we will be able to register MiSelect as a class-I device before the end of 2017, while we plan to subsequently apply for a class II or class III registration. In this regard, we are about to start a clinical trial in the CTC field to support our class-II or class-III certification. Besides opening up the door to international markets, receiving these certifications and regulatory approvals will also prove that MiCareo – after more than five years of hard work – has managed to translate a groundbreaking technology into a marketable product.

Second, we want to develop strategic partnerships and collaborations with leading pharmaceutical and biopharmaceutical companies. For pharma companies involved in liquid biopsy, precision medicines, and immunotherapies, we want to establish MiCareo as the best company that can provide them with the information and tools they need to better and faster develop their innovative treatments.

In the mid-term, we are also focused on identifying the right marketing and distribution partners in key international markets. Given that we are very science-oriented company, more than 70 percent of our employees work in R&D and our business development capacity does not allow us at the moment to fully leverage the great potential of our product. We are then looking for any kind of partnerships that would allow us to bring our products onto the global stage, in order to complement our product's positioning as a companion diagnostic for the clinical development of immune-therapies and novel oncology precision medicines and/or liquid biopsy-related products.

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