Interview: Michael H.J. Lai – Founder, Body Organ Biomedical Corp., Taiwan



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19.06.2017

Tags: Taiwan, Body Organ Biomedical, Ophthalmology, Biotech

Michael H.J. Lai, Founder of Body Organ Biomedical Corporation, discusses Ologen's success as the first ever eye tissue repair product and highlights the importance of global exposure for Taiwan-based companies.

Can you introduce the company to our readers? What was your vision at the time you started the company?

Body Organ Biomedical was established in 2007. As I met a lot of leading ophthalmologists from the US and Europe in the past, I was familiar with the medical demand in this field. Great demand for cornea, biocornea and tissue repair served as an inspiration to start up the company. I already had a background in tissue engineering- I have been involved in this field for almost 30 years- and I wanted to start my own business in an innovative and creative field. At the time, I noticed that doctors use one chemotherapy drug off label after the eye surgery. It was common to use it for scar formation prevention. I acknowledged that collagen scaffold was an ideal product for tissue repairs, but strangely, nobody used it. At that moment, I identified a market opportunity and organized my team to start working on collagen matrix. We established a brand name Ologen for collagen matrix- first global eye tissue repair product. The results from animal study were successful. We attended the ARVO seminar in 2006- international congress gathering biggest eye research associations. I had a chance to meet a professor from Leiden University with whom I discussed the demand for eye tissue repair. She mentioned artificial cornea as a convenient

solution for doctors and patients. The research was conducted shortly after. Following the successful research, we started the company focusing on artificial cornea.

You provide regenerative solutions in in the areas of orthopedics, dentistry and ophthalmology. Can you give us an introduction into your product portfolio?

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Our first product in the ophthalmology area is Ologen collagen matrix for tissue repair. The product is introduced and distributed in 40 countries worldwide- it is the world's first eye tissue repair product. However, the product is under insurance reimbursement review currently. Doctors require long-term performance data; final outcome after five years is required. During this period, we have to collect the data, introduce the medical environment to the product and educate them. We are also developing a product called Biocornea. This product is currently under clinical trial in Germany. Our aim is to be a substitute of human cornea. The main material we use for product development is fish scale. This year we will start an animal study in Denmark and Taiwan for a product called PK (Penetrating Keratoplaty) Cornea Transplantation. At the same time, we develop cornea patch for glaucoma drainage devices. Glaucoma drainage devices often cause corneal erosion. Therefore, a patch is required to cover it for corneal replacement. In the ophthalmology area, we have three products in development and one on the market. We are also working on dental and orthopedic products- the gingiva regeneration and membrane used for guided bone regeneration and tissue repair and a bone fitter for bone and tissue regeneration. Fish scale will also serve as a main material for orthopedic products. Dry eye treatment is the new area we plan to enter soon- this is currently under research. Our products are sold to hospitals via distributors. Best performing markets are Germany and Spain – in two months we will file for approval in Taiwan.

Are you considering new countries after Taiwan?

Yes, Brazil and China are in consideration. We have just finished our clinical study for Ologen collagen matrix after four years and by the end of the year we will file for CFDA approval. In India and Netherlands we run the subsidiaries and as already mentioned, this year we are expanding to China. Afterwards, we plan to expand our operations to Brazil, Japan and Korea.

Do you have any upcoming product launches in the near future?

Yes, in two months we are launching our dental product. Starting this year, we plan to introduce at least one product per year.

What is the role of your subsidiaries in the overall business strategy?

We apply for the US FDA through Dutch subsidiary. We also use it as a license holder for the Indian company and to expand our operations to China. We possess a holding system that features subsidiaries used for licensing or marketing and sales. In India we run another company for assessing the market. Biomimiq is our different unit that specializes in artificial skin and collaborates with big pharma.

Can you describe your R&D strategy?

Our aim is to make a different type of bio scaffold for tissue repair and tissue engineering starting from eye and dental products. Our expertise is using biomaterial for different bio scaffold products used in tissue regeneration field. Also, we are currently focused on entering the dry eye treatment area. This is a different category because bio scar is used for bio surgical needs- intervention. In the future, we will focus more on medical electronics that serves as a prevention.

A lot of Taiwan headquartered companies tell us their growth vastly rely on partnerships. What is your partnership strategy?

Our partners are distributors in the eye market. All the distributors in the eye sector are individual. We have a lot of partners that also include universities worldwide, such as LUMC in the Netherlands and Cologne University in Germany.

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What is your competitive advantage? Why should potential partners choose to collaborate with you?

We are an innovative company that is using fish scale to develop high advance technology products. The main material for cornea is collagen – featuring mechanical strength and transparency. Scientists and doctors have been struggling for years due to a lack of cornea. They tried to find a solution which they couldn’t. Initially, we invested a lot of money to form different types and layers. However, we failed many times. Finally, after numerous defeats, I had a final dinner with my team due to the inability to develop a cornea substitute. One of our managers ordered a fish and a piece of scale stuck to his chopstick. He shared a wild idea about developing a cornea substitute using fish scale. As we had already failed so many times, I felt I have nothing to lose if trying one more time. Finally, this structure turned out to be very successful and very similar to human cornea. Afterwards, we started many international collaborations with universities and received grants. Horizon 2020 (focusing on future products in 2020) is a funding from European

Commission that we received. This funding features 300 applicants and only six are awarded. We are the first Taiwanese company to receive this type of funding grant. Additionally, this is our second grant – the first one was EP7.

What are your strategic objectives/priorities for the upcoming years?

Our strategic objective is to make Ologen collagen matrix a first line of treatment for glaucoma in developing countries. A phenomenon occurring in developing countries could be described as a lack of patient's comprehension for medical treatment. Consequently, their health is not managed in the best possible way. We want to increase the level of education and understanding when using our product as it is useful and efficient. Secondly, our aim is to finish biocornea clinical trial in Germany and get an approval to save patients from blindness. Entire business strategy and product development is always focused on the same mission: saving people from blindness.

The medical device industry will hit $398bn in 2017 and is predicted to show a strong growth till 2023. As someone who spent most of his career in the field, how do you see the industry evolving over the years? What are the main trends that will drive future growth?

The industry is continuously growing in the past 30 years due to growing demand, innovation and population, with the tendency to continue its growth in the future. Innovation, aging population and overuse of electronics are some of the trends that will drive the future growth. Eye health is gaining importance. The trend of overusing electronics leads to eye strain and increasing eye temperature. Consequently, people develop diseases at an earlier age. Glaucoma patients are underdiagnosed – more than 50 percent of glaucoma patients don't know they suffer from glaucoma. Overuse of electronics might increase the number of blind people in the upcoming years. Therefore, Body Organ Biomedical will introduce the eye temperature measurement that relates to dry eye, myopia and short vision. This technique might help in glaucoma prevention.

How do you see Body Organ Biomedical contributing to the local innovative ecosystem of Taiwan?

We are a unique Taiwanese company representing our brand globally. Not many local companies globalize, they stick to domestic market. Taiwan has a lot of great scientists, but no so many globalized managers. Body Organ Biomedical, even though being a small company, has a very global exposure.

As a Founder and Chairman of the company since 2007, what makes you particularly proud till this day?

Providing good treatment and developing an innovative and creative product that features advanced specifications makes me very proud and satisfied. However, the ultimate goal is to make Ologen globally accepted and the highest ranked brand in the world. Consequently, we can provide the best treatment and save a lot of people from blindness.

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