Leo Liu – President, GeneReach, Taiwan

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26.08.2019

Tags: Taiwan, Medtech, GeneReach, Diagnostics

Leo Liu, president of GeneReach Biotechnology Corp, shares the story of the diagnostics startup and explains his strategy to transition the company from a leading animal health point-of-care device manufacturer to a firm with a growing footprint in human health.

Please begin by introducing yourself and the history of GeneReach.

In 1986 I went to the US and was trained in the field of animal science. At this time the biotechnology was just starting to boom. During my studies at Oregon State University, I started to see the applications of polymerase chain reaction (PCR) testing in the field of genomics. I sense the potential opportunities of genetic technology in animal science and my professor at the time was also exploring this area. Therefore, I began to delve deeper and learn more about genetics.

When I returned to Taiwan in 1990, the country was in the beginning stages of introducing a lot of new technologies from the US and Europe. This was the second attempt of Taiwan to embrace biotechnology, the first try during the 1980s was unsuccessful. Taiwan's traditional industries of fabric, machinery, and eventually computer manufacturing so investors did not understand the unique nature and development timelines of the biotech industry. Therefore, when investors did not see immediate results in three to five years, they pulled their funding, not allowing the industry to truly take off.

In 1993, I was approached by American investors looking to expand the success of biotechnology in Asia, so together we made our first venture into human diagnostics. At first, we were unsuccessful, until we discovered opportunity in aquaculture. This was a better space for a small startup as there was a high unmet market need and regulations were much less stringent.

We signed an agreement with National Taiwan University and the National Science Council for collaborative development. With Dr Lo, a leading scientist in shrimp disease diagnostics, we used to the currently existing technology to develop a diagnostic solution in aquaculture. Working with aquaculture farmers, many also had other livestock which was then how we began developing diagnostic tools for cattle, pigs, and even companion animals.

At the time, most DNA diagnostic tests were done from the lab that requires a high investment and resource allocation which is just not practical for the animal industries. Additionally, most diagnostic players from the US and Europe were focusing on lab testing, so there was little room for a small startup. Therefore, in 2008 we began to focus on point-of-care diagnostic tools, a much less saturated market segment. Being a Taiwanese company, we were able to take advantage of the country's strong ICT background to effectively develop this technology.

What competitive advantages does GeneReach have as a Taiwanese biotech company?

In Taiwan, we have a good opportunity to work among a range of different industries, such as fine machinery. There are many SMEs who are very keen on establishing cross-industry collaborations, especially in emerging fields. Having access to a reduced scale of resources necessary for the development stage can be a big challenge for startup companies. However, in Taiwan, startups can cooperate together to work on small scale development, making the costs of R&D much lower than in countries like the US. The combination of Taiwan's strength in fine machinery and vast expertise in life sciences are driving forces for the success of the nation's medical device sector.

GeneReach's products are built around your core Insulated Isothermal PCR (iiPCR) technology. What is the uniqueness of this platform?

Our principle device, POCKIT™, is a qualitative polymerase chain reaction (PCR) amplification and detection system based on Insulated Isothermal PCR (iiPCR) technology, which applied the concept of Rayleigh-Benard convection to drive PCR by a single heating source at the bottom of capillary tubes. Unlike conventional PCR, which requires several cycles of heating and cooling, iiPCR is

accomplished through the temperature gradient generated from the thermal convection with its reaction time significantly reduced.

POCKIT™ is intended to provide qualitative detection of nucleic acid targets using fluorescence-based iiPCR reagents and is equipped with up to two optical channels (520 nm / 550 nm) for multiplex detection. The qualitative results are readily displayed on the touch panel monitor without post-amplification manipulation.

To develop on-site diagnostics, we understood that the technology must be simple and easy to operate. Our vision is to create a link between diagnostics and biosecurity. Developing biosecurity is much more effective than the traditional reactive approach where care measures are only taken when problems arise.

What is your strategy to make the transition from animal health to human diagnostics?

Over the next three to five years, our primary income will continue to come from animal science. The core technology in diagnostics for animal and human health is the same, but human health is a much more challenging space when it comes to regulation. However, the experience and knowledge we are gaining from the animal science field will be invaluable as we expand into human diagnostics.

Additionally, we have several partnership agreements with European companies to develop our capabilities in the space. Recently, we have achieved CE certifications for our technology. Outside of Europe CE IVD accreditation is highly valued in Middle Eastern and Southeast Asian markets. This strategy not only allows us to have access to the EU but also many emerging markets where we will have a better opportunity to establish ourselves.

We are now working on conducting clinical trials in Taiwan for out human diagnostic equipment while looking for partners in various markets to better understand the regulatory landscape and how the registration procedures as a medical device company in those countries. We are also attending international exhibitions and tradeshows to raise our image. Additionally, we are producing numerous publications to build the credentials of our platform and portray the effectiveness of the technology.

As a newcomer to human health, how is GeneReach able to make a space for itself in the market between MNC heavyweights who have much stronger recognition and more resources?

Although large medical device players are strong in IVD they are not very well positioned in point-of-care diagnostics, especially when it comes to genetic testing. Typically, they operate in this field through M&A or partnerships. Therefore, we are hoping that by building our profile we can create collaborations with leading diagnostic companies. Since our iiPCR is a platform technology, we can work with these market leaders as an OEM/ODM provider for a variety of different disease areas.

What makes GeneReach a partner of choice for future collaboration?

In terms of biosecurity diagnostics, POCKIT™ is very user-friendly and cost-effective. Cost-effectiveness is key in the diagnostics sector and it is one of the true advantages of Taiwanese companies in the biotech industry. The experience that has been accumulated in fields like ICT manufacturing and biomedicine over the years enables us to produce innovative technology at the right price point.

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