Interview: Lee-Cheng Liu, President & CEO, EirGenix, Taiwan

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Dr. Liu, President and CEO of EirGenix, talks about why he sees Taiwan as the ideal market for a CDMO like Eirgenix, why he believes that despite the skepticism, biosimilars will be able to overcome the initial barriers, and where he sees EiGenix in the next several years.

What has been your vision for EirGenix since its founding?

As a contract development and manufacturing organization (CDMO), we focus on technology. We hope that, in the future, we can offer the same kinds of services as Boehringer Ingelheim or Lonza. We donâ??t necessarily want to be as big as them, but we want to be as good as them. Our emphasis is on quality rather than size.

Another pillar for EirGenix is the development of biosimilars. In order to push our manufacturing technology to acceptance on the global stage, we need a product. We have PIC/S GMP certification, but that is not enough. We need to be inspected by FDA and EMEA regulators, which will be triggered when a product is launched to the market through your manufacturing facility. They would be turned as crucial credentials to truly win the interest of international clients. Biosimilar development is like a springboard for us.

We will look for partner(s) on our biosimilar pipeline with regional pharma or global pharma companies. It may be possible that our work may lead to the development of novel drugs as wellâ??although we will have to be very selective in terms of who we collaborate with.

As the business moves forward, we may consider spinning off drug development into a separate entity. Services and development have very different return profiles, and different investor profiles as well.

When the biopharmaceutical industry thinks of CDMO services, why do you believe Taiwan comes, and should come, to mind?

Taiwan has a very successful history in small molecules API manufacturing. Some of the countryâ??s leading API manufacturersâ??companies like Formosa Laboratories and ScinoPharmâ??started out as contract service providers, and became highly adept in certain small molecule technologies.

Biopharmaceutical capabilities were slower to develop in Taiwan. However, I think now is the time for Taiwan to make biopharmaceutical CDMO a focus point. As more and more new biologics and

biosimilars are developed both in Taiwan and around the world, service companies with strong development capabilities are in high demand.

At EirGenix, we have a number of competitive advantages. Firstly, the 38-person team we inherited from our recent acquisition of the Development Center for Biotechnology (DCB)â??s cGMP Biopharmaceutical Pilot Plant Facility (BPPF) is fantastic, and has accumulated ten years of process development and production experience in biologic products. Nearly every single protein compound developed in Taiwan has passed through our laboratories or production plant for certain services. The team has been busy serving DCB and domestic needs until now, but today we are actively expanding our capabilities to serve the global market as well.

Secondly, our strategic partner is Formosa Laboratories. Formosa has one of Asiaâ??s largest high-potency production capabilities. They are capable of translating projects from the laboratory, to the pilot plant, to commercial manufacturing. Lately, one of the hottest areas in biologic development is Antibody-Drug Conjugates (ADC), and to succeed there, you need both large and small molecule experience. The small molecule element requires high-potency manufacturing capability, so itâ??s a perfect fit for Formosa to provide customer made either linkers or payloads (high potency chemical compound or toxins, and bio-conjugation. As EirGenix, we will take care of the large molecule partâ??Mabs or proteins with specific targeting.

There are perhaps 30 ADC drug compounds in early development around the world today. Many of the pharmaceutical companies that are working on them are relatively small as emerging venturers. Big Pharma often has its own in-house development and manufacturing capabilities, but the smaller players need to outsource most of their CMC activities to contractorsâ??and there is a lack of service providers out there that have the know-how and facility to work with these drugs. We are currently holding discussions with several companies, and figuring out how we can collaborate with them on their ADC pipelines.

To answer your question: do people think of Taiwan for biopharmaceutical CDMO services? That is something weâ??re working on now. We have to create those linkages. As I noted, our history in small molecule services is quite good. It can serve as a steppingstone for us to develop the next frontier.

Some experts are skeptical about the future of biosimilars: they say that manufacturing costs, marketing costs, and regulatory pathways will prove to be much higher barriers than the industry expects. What is your view on the subject?

I think itâ??s just a matter of giving the market a bit more time. Around 1985, monoclonal antibodies had a well-publicized failure as well, and skeptics were saying that that was the end for antibody drugs. But scientists went back to the drawing board, and things changed. Genentech once called itself as the best protein drug company in the worldâ??but now, they are truly a mono-clonal antibody Company.

The big hurdle is less on the manufacturing side, and more on the marketing side. If the industry can overcome interchangeability issues with regulators, it will be a different ballgame. Currently, FDA and EMEA officials in particular put very stringent requirements on these drugs. But Iâ??ve spoken to a lot of people within the regulatory system, and they say that they are being cautious to protect biosimilar field to avoid anything bad from happening that would ultimately hurt biosimilar development in the future.

The acceptance onto the market of a biosimilar drug candidate has latched onto similarity to the originator drug: and with the experience of trial and error, companies are getting it right more and more often. That experience, in turn, drives down development costs. In some markets, for instance,

we have seen the price of Human Growth Hormone (HGH) biosimilars listed at prices as low as 40 percent of the originator price. That is a great relief for the payers.

Each country has its own healthcare challenges. The way individual governments respond to biosimilars will be a driving force behind their palatability. But the fact is that, in the long term, biosimilars *must* be successful in order to drive down healthcare costs.

Do you see a clear path to the Chinese market?

With the passing of the ECFA agreement, we hope that there will be more discussion between regulatory agencies on both sides of the strait. Currently, if you want to market a biological product in China under Chinese standards, you have to manufacture it in China. We hope negotiations will bring about recognition of Taiwanese certificates, such that drugs that are accepted into the market in Taiwan will be automatically accepted in China.

Such a development would greatly change the landscape of the Taiwan biotech industry. I say that because in Taiwan, IP enforcement is very stringent. Our workforce, moreover, is extremely diligent and honest with higher working ethics. The spirit of cGMP is really a system and a culture to ensure a product quality instead of a product quality by testing. The FDA can shut down your plant not because they find something wrong with your product by testing, but because you didnâ??t enforce the quality system. If we think about that, we realize that if we get the clear window to China, Taiwan, moreso even than Singapore, might be the best place in the region to manufacture biopharmaceuticals.

What was your experience with raising funds in Taiwan?

Actually, my experience was quite remarkable. We raised 18 million USD in just two months, from Formosaâ??which owns 20 percent of the companyâ??Venture Capitals, and investment banks. I have never seen a fundraising round go this fast in the US.

Itâ??s a great time for biotech in Taiwan today. Many companies not just in Taiwan, but also regionally and even as far as the US, are looking here for seed capital. More and more investors in the country are willing to give their money to this industry. Some time ago, investors in Taiwan would always ask if they could see a return within two or three years. Now, they ask about the product potential, and look for return in five to seven years. Now, they seem willing to wait.

What is next for EirGenix?

We want to do business globally. Our partner, Formosa Labsâ??which owns 20 percent of EirGenixâ??has the same vision. We want to meet and exceed an international standard.

We are in the planning stages of a large-scale protein production plant. We will build it either in Taiwan or China. With that facility in place, we will be able to do even more for the global biopharmaceutical industry.

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