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

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Lee-Cheng (L-C) Liu, President and CEO of EirGenix, one of Taiwan's fastest growing companies in the biotech field, documents the progress made in the set-up of EirGenix's new commercial biomanufacturing plant, which will become the largest facility of this kind in Taiwan, while the company is about to start the phase III clinical trial of its own trastuzumab biosimilar and is actively looking for strong commercial partners to distribute it in all international markets, with a market entry set up for 2020.

EirGenix's business model is based on two main pillars: contract development and manufacturing (CD&M) services and the development of our own pipeline of biosimilars. What would you highlight as EirGenix's main achievements in these two fields?

Over the last four years, our CD&M services revenues have been skyrocketing from NTD 8 million [around USD 250,000] in 2013 (i.e. the year we acquired the biopharmaceutical pilot plant facility of Taiwan's Development Center for Biotechnology, DCB), to reach NTD 252 million [over USD 8 million] only four years later, in 2016. More importantly, from 2013 to 2016, EirGenix's annual signed contract value soared from NTD 25 million [around USD 800,000] to NTD 330 million [almost USD 10.5 million]. Our current process development and manufacturing facility is now almost running at full capacity, especially as manufacturing clinical batches requires keeping a relatively

high level of flexibility. Because of our current limitations in terms of production capacity, we have become very careful when it comes to choosing new customers and scheduling the execution of our contracts, as we do not want to lower the quality of our delivery or increase our turnaround. As a result, our targets for 2017 are relatively conservative in comparison to our previous growth rates, and we want to reach NTD 300 million in revenues [around USD 9.7 million] and NTD 400 million [around USD 13 million] in terms of annual contract value. EirGenix and its 128 employees now truly stands as an international company: overseas customers already make up around 25 percent of our client base and over 40 percent of our total revenues, as EU, US, or Japan-based customers usually come to us for larger projects than Taiwanese companies. We however remain utterly committed to serve Taiwan's thriving biotech industry and treat all our customers with an equal ambition to exceed their expectations. Additionally, we are now in contact with some Big Pharma companies, which have been displaying a rapidly growing interest in our services.

Looking at our own product pipeline, we now hold seven products in development, including four biosimilars, one antibody drug conjugate (ADC) that is a me-too biobetter co-developed with Formosa Laboratories, a carrier protein that is an important intermediate for the development of new vaccines, and –finally- a new subcutaneous formulation of an existing biosimilar. We recently completed the phase I trial of our most advanced compound, EG12014 (trastuzumab biosimilar), a monoclonal antibody used to treat breast cancer. We are currently preparing a phase III trial and expect to initiate patient enrollment by the end of 2017. As a company, we do not hold the capacity to market and distribute this product by ourselves, so we are actively looking for strategic partners that will handle the commercialization of this biosimilar in the US, EU, Taiwan/SE Asia, and Japan. In this regard, we concentrate our efforts on mid-size pharmaceutical companies that will perfectly complement our own specificities: very strong marketing and sales presence in the aforementioned markets but without or very limited R&D capacity in the biosimilar area. In terms of upcoming timelines, our objective is to complete this phase III study by 2019, and submit applications of BLA in the US and MAA in the EU; we expected to launch EG12014 to the market in 2021.Given these objectives, we absolutely want to find the right commercial partners before the completion of the phase III trial.

[Featured_in]

As EirGenix is rapidly advancing in the development of its biosimilar portfolio with a first market entry set up for 2020, holding a commercial biomanufacturing facility becomes evermore crucial. Have you been moving forward on the development of this critical asset?

Our current state of the art biofacility provides 500L/1,000L scale GMP manufacturing, but we are

indeed rapidly advancing in the set up of our commercial-size plant. We actually started working on the design of this new facility back in 2015, while is construction started in December 2015. This new plant will be located in the Zhubei Biomedical Science Park which is next to “Taiwan’s Silicon Valley”. Our main focus when designing this new plant was to ensure it would be very flexible. When the facility will be completed, it will hold two mammalian cell expressed protein production plants, each plant gathering 3 trains of 2x2000L SUB (single use bioreactor) systems, as well as a flexible downstream purification systems with a 8x turn down ratio that will be able to handle a minimum of 2Kg and a maximum of 16 Kg of target protein per batch. Finally, this new plant will also hold a microbial expressed protein production plant with a 1000L fermentation system and two downstream purification suites.

We want to ensure that this world-class facility, which will stand as Taiwan’s largest biomanufacturing plant, will be up and running by the third quarter of 2018. In the grand scheme of things, this plant will first and foremost handle the manufacturing of our upcoming biosimilars. As we want to bring our first products onto the global market in 2021, we have to ensure the plant will be ready to start its operations before the end of 2018, as regulations stipulate that part of the material used for late stage phase III clinical trials have to be produced in the commercial plant that will ultimately manufacture the final products.

In addition to our own products, we however ensured this new plant would also hold the extra-capacity to handle the commercial or late stage product production of our partners’ products. Although next year will certainly stand as a transition year, we are already talking with some of our existing customers about the opportunity to expand our partnerships to the commercial phase for their most advanced products.

Cost-efficiency stands as crucial competitive advantage in the biosimilar area. What are the main rationales that counted toward your decision to build this facility in Taiwan- and not in China, for example?

Quality is our main driver. From an expertise standpoint, we considered that it would be easier to find highly qualified people in Taiwan, whereas China is currently facing an important shortage of talents in the biomanufacturing field, to the extent that Chinese headhunters are aggressively recruiting Taiwanese talents at our doorstep.

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Second, in terms of GMP compliance, Taiwan probably holds a better reputation than China, while our country’s regulatory agencies such as TFDA boast a great recognition onto the international stage. Finally, Taiwan’s government and local VC funds still are important shareholders of our company, which favored our decision to further increase our manufacturing capacity in Taiwan.

What do you see as EirGenix's main competitive advantage that has been driving the success of its CD&M service offering and leading its revenues to grow 4100 percent from 2013 to 2016?

Timing has been a crucial success factor. In Taiwan, a large number of biologic projects are currently at the clinical development stage. Given their international ambitions, Taiwanese companies cannot afford to partner with service providers that do not meet the highest quality and efficacy standards. When we set up EirGenix, there was clearly a lack of local biomanufacturing capacity, but also probably a trust issue as local companies were simply not used to work with local partners for such a critical aspect of their drug development projects. As a result, local biopharmaceutical companies would rather choose international service providers. In this regard, our success proves that EirGenix has been able to build a great reputation for itself on the Taiwanese market and nurture a relationship based on mutual trust with local customers.

Furthermore, we place the utmost emphasis on tailoring our services and delivery to the exact needs of our clients. EirGenix's approach is that contributing to our partners' success is our priority. It goes beyond a simple slogan or branding effort: it truly is at the core of all our meetings and the way we conduct our operations on behalf of all our customers.

While most of our international competitors are essentially focused on Big Pharma and biotech companies, we have been particularly eager to focus on serving medium/small enterprises – a market niche that was clearly underserved. Servicing emerging companies moreover requires being extremely flexible, which most of our competitors cannot do. This positioning and our quality approach have allowed us to gain a respected position in the market: after only four years in operation, we already hold returned customers that now trust us throughout their development process.

You already hold seven products in your R&D pipeline. How have you been building your pipeline to make it attractive to potential partners?

As you know, our most advanced biosimilar in development is EG12014 (trastuzumab biosimilar), sold under the brand name Herceptin® by Roche, whose patent in the US will expire in 2019.Roche has also developed Perjeta® (pertuzumab), a monoclonal antibody used in combination with trastuzumab, for which we are also developing our own biosimilar. As displayed by the latest clinical trials performed by Roche, combining Perjeta® and Herceptin® provides greater outcomes than the single us of either of these products.

They are several companies around the world developing biosimilars of Herceptin®. EirGenix entered the development race later than some of our competitors, which some of them started developing their products as early as in 2011, while EirGenix was only founded in 2013. Although

we are not in the top 3 of the most advanced companies involved in the development of this biosimilar, our portfolio's positioning should be particularly appealing to potential commercial partners, as we will be able to provide them with the combination of trastuzumab and pertuzumab. Beside the ability to offer this treatment package, we are also developing a new, subcutaneous formulation of pertuzumab.

Furthermore, in the development of Antibody-Drug Conjugates (ADC), both large and small molecule expertise and experience are required. In this regard, our strategic partner Formosa Laboratories holds one of Asia's largest high-potent API production capabilities, and they are capable of translating projects from the laboratory, to the pilot plant, to commercial manufacturing. The small molecule element requires high-potent manufacturing capability, and Formosa will then handle the development of linker and payload, while, as EirGenix, we take care of the large molecule part—Mabs or proteins with specific targeting.

> "In terms of new products that could soon enrich our R&D pipeline, we also consider the opportunity to in-license new compounds and form co-development partnerships with some of our customers."

Without any doubt, working on our trastuzumab biosimilar has been a great learning experience for our company, and we have been greatly improving our quality profile and development expertise throughout the development of this important product. We now expect that this accumulated experience will speed up the development of our other biosimilars. In terms of new products that could soon enrich our R&D pipeline, we also consider the opportunity to in-license new compounds and form co-development partnerships with some of our customers.

What are your strategic priorities to ensure EirGenix does not experience a crisis in growth?

In our long-term business plan, we expect that CD&M service activities will make up only 30 percent of our revenues in ten years. To fulfill this objective, we need to move forward on the development of our entire pipeline, and especially EG12014, to ensure it completes its phase III trial over the second half of 2019. For biosimilars, the success rate for phase III trials is usually extremely high, as the most critical step is to prove that the biosimilar product shows highly similar product profile compared to the originator. As a matter of fact, among the 19 biosimilars already approved in Europe *[where Herceptin® went off-patent in 2014, e.d.],* none of them failed in phase III trials. In this regard, our main focus is on the perfect execution of these trials and ensuring we respect our timelines.

On the other hand, forming strategic alliances with ambitious commercial partners is our other key priority. In all markets we consider, whether it is the US, EU, Japan, Taiwan/SE Asia, or also the

MENA region, our ability to from successful marketing agreements for our first compound will very likely create opportunities for a broader franchise approach, based on our unique combination of trastuzumab and pertuzumab.

How would you summarize EirGenix’s positioning on the global stage?

From our CD&M business, where we help our clients to ramp up the development of their new biologic compounds, to the development of our own biosimilars, EirGenix has become the new hub in Asia for biologic product development and manufacturing. In this regard, we are eager to develop new collaborations and partnerships with pharmaceutical companies all around the world.

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