Interview part one: Rongjin Lin, Chairman, TTY Biopharm, Taiwan

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In the first part of this two-part interview, the Chairman of TTY Biopharm considers the success of his long-term strategy to streamline TTYâ??s portfolio and focus on the companyâ??s strengths, and talks about the opportunities in Asia for companies that have followed a similar path to TTY. To read the second part of the interview, click here.

Is biotech a viable industry for Taiwan?

I believe that it isâ??the question, however, is how we should position ourselves. As a country, we have to find our niche.

Letâ??s take the example of TTY. I have been at the helm of this company for about 20 years. When I joined the business, it was bankrupt. We were a pure generics player that had 220 products on the market, despite a headcount of only 170 people. In the generics business, 220 products is a ridiculous number for a small player! Generics companies need to offer low cost and high qualityâ??and without critical mass, this goal is unachievable.

In one month, I removed 190 products from our portfolio. I chose to focus on only 30 drugsâ??and among the 30, six leading brands brought in the majority of our revenues. I restructured our production operation: in the same space where we once housed seven manufacturing lines, we reduced to three. The company returned to positive cash flow within eight months. Within four years, we were ready for the next step.

We shifted to medium-barrier products. At the time, as part of its growing program of support for the biotech sector, the government had announced the so-called â??tNCEâ?• regulatory system. tNCE products were those that had been launched in other countries, but had never been introduced in Taiwan. The state allowed domestic generics companies to copy such products without patent issues, and offered five years of data protection.

TTY adopted the tNCE model around 1998â??but by 2000, I began to think that there was no future in it. Five years of protection, after all, is inherently temporary. We needed something more sustainable. We got to work on high-barrier technologies: liposome and PLGA platforms. Such products demand a dedicated production line, as well as a clinical trial or bioequivalence study. Companies that play in this arena require very strong regulatory and clinical knowhow, as well as the resources to commit to a substantial amount of capital investment. In 2005, I set a goal for TTY: by 2015, we would become the top liposome and PLGA manufacturer in the worldâ??while maintaining the same factory size.

How have you moved to realize that goal since then?

In 2008, we also decided to spin off the production of all non-cytotoxic agents in our portfolio, because cytotoxic drugs require a dedicated production line. We focused our internal manufacturing efforts on three platforms: cytotoxins, liposomes, and PLGA. Having made this choice, we integrated all production from the functional excipient to the finished product. Bolstered by our partnerships with multinational companies, we are on track to achieve our 2015 targets. TTY is set to become the leading liposome and PLGA manufacturer in the world.

Leveraging our liposome capability, we are now increasingly turning our focus to new product development. I recently spun off PharmaEngine to develop our first NCE. The company has been quite successful thus far: its product is now licensed out to the US-based company Merrimack Pharmaceuticals, and PharmaEngine has undertaken an IPO.

We have focused on just one or two technologies to take our company to the global stage. This kind of strategy makes things easier for your manufacturing effort, and easier on your capital investment. We donâ??t believe in â??more, more, moreâ?? investment. Instead, we believe in accumulating knowledge, and developing our people and capabilities.

I know that for the next generation of liposome products, such as monoclonal antibody drugs, we are late movers. TTY is a pure chemical company. Luckily, in 2000, I made my first investments in an enterprise that was an early mover: Mycenax. I am now the chairman of the company and a majority stakeholder. Againâ??I donâ??t believe in investment for the sake of investment. I believe, rather, in having focus, and I believe in surrounding myself with high-quality talent.

How do you assess the potential of the generics market?

For Taiwan, there is no future in simple generics. Price cuts will compound in the coming years, and only volume growth will be able to sustain companies that compete in this area. We do not have the critical mass or the vertical integration. If we want to compete in the generics market today, we have to compete in specialty niches. We have to compete based on high-barrier products. Luckily, as TTY, our investment over the last seven yearsâ??from 2005 until todayâ??has put us in a strong position in the specialty generics market. We have won the interest of multinational companies and are cooperating with them.

And yet, around 2010, the multinationals began to step into the specialty generic field. They are late, but they will catch up quickly. After 2015, â??difficultâ?? generics will become â??simpleâ?? generics! So even here, TTY and Taiwan have only a very small window to compete. That is why we have jumped to developing patented drugs.

In 2008, TTY moved to â??category management.â?? We focused on oncology to become a global company. We developed relationships with key opinion leaders, and conducted numerous clinical trials. Our quality and our knowhow has become very strong, and we know how to balance regulatory, commercial, and scientific functions. Achieving this balance is the key to drug development. Although our current approach may not yield new drugs that will be considered â??breakthroughsâ?? in the West, they will be more than good enough to offer to emerging countries. Perhaps we wonâ??t be able to offer superior efficacy, but I believe we will be able to offer, say, superior safetyâ??these and other advantages will help us penetrate the market.

I donâ??t believe that a country like China will follow the US model, adopting such â??luxuriesâ?? as pharmaco-economics and so forth. Given its current stage of development, if China takes a Western approach, it would totally crash! The country would become bankrupt. For this reason, I believe that we can find a sweet spot in Asian markets between generics and breakthrough innovation: similar efficacy, improved safety profile, and a price that is reasonable. China and other emerging countries will encourage the uptake of such products over the next ten years.

But my vision does not stop there. By 2020, if a company like TTY wants to continue to survive, it needs to have truly innovative products in its pipeline. In 2008, we invested US$100 million in China, developing a dedicated business model for the market that involved the construction of a domestic manufacturing facility and the incorporation of the entire value chain under one umbrella. In China, we became a Chinese company. Currently, we are much better than the indigenous Chinese players at commercialization: in terms of regulatory affairs, an international standard of thinking, and etc. We have to use this time advantage to build a foundation over the next five years. Most Chinese domestic companies are interested only in Chinaâ??certainly, the domestic market is big enough for them to swim. TTY, on the other hand, can use Chinese data to prepare ourselves for global innovation.

Today, TTYâ??s cash flow is very powerful, thanks to the strength of our marketing and sales team. We are a category leader in two or three oncological niches both in Taiwan and China. We have integrated the advantages of the two regions, including a naÃ¯ve patient population for conducting clinical trials. This cash flow will give us the leverage we need to get to the next stage of our evolution.

Why do you say that a company like TTY needs to eventually become truly innovative to survive?

Firstly, as I began to mention, our strategy is always to have a cash cow before we move forward. We started with pure generics, and moved to branded generics with tNCE. We then moved to high-barrier, specialty generics. This latter strategy has already taken us globalâ??because for now, the market needs us. Multinational generics companies that have not yet established themselves in the specialty field look to help us with regulation, TMF, DMFâ??everything. Of course, the price they offer us is not too high, but nonetheless we get a good opportunity to play. Our factory is registered worldwide, because if we partner with a multinational, they have to ensure we are registered in every country where they distribute our products.

And yet, even with our current success, we will surely hit a wall without patented products. TTY will never become another Pfizer: we will focus on China and Taiwan, where we will conduct drug development and marketing & sales operations. Elsewhere in the world, we will cooperate with multinationals through out-licensing. China is big enough for us for the next twenty or thirty yearsâ??after all, China is set to become the second-largest pharma market in the world after 2020.

With that said, I will again stress that our innovative products can nonetheless have a global reach. I believe that Taiwanâ??s medical standards, coupled with Chinaâ??s resources, will be able to produce viable international drugs.

What is your opinion of the Indian paradigmâ??where several major players, much like TTY, have sought to move from generics to innovation?

I think that the Indian generics companies that are moving towards innovation are too big. I donâ??t believe that their scale is conducive to drug development. Their networks are too complicated. It is for this reason that I chose to spin off PharmaEngine, or keep the competencies of a company like Mycenax outside of the official TTY Group. To directly integrate these capabilities into the group would take perhaps ten years; to align them into my value chain takes one year at most!

I believe in speed. Too big means too busy, and too busy means too slow. Mid-size companies have the winning formula in the innovation space. If I could, I would separate as many functions as possibleâ??the only reason I will retain China and Taiwan marketing & sales functions within TTY is because our team is an ear to the street for us. They will allow us to keep abreast of unmet medical needs.

To read the second part of this interview, click here.

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