Interview: Peter Tsai – Founder, CEO & Chairman, Orient EuroPharma (OEP) & Orient Pharma (OP), Taiwan

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20.04.2017

Tags: Taiwan, OEP, OP, Pharma, Healthcare, Southeast Asia, Strategy, Drug Development, Manufacturing, Distribution

Peter Tsai, founder, CEO, and chairman of Orient EuroPharma (OEP), one of the leading groups of healthcare companies in Taiwan, provides insights into his strategic vision to double the group's revenues within the next five years and nurture the long-term growth of the company he founded in 1982, while OEP's activities now encompass drug development, small-molecule manufacturing, as well as OEP's historical leadership in the distribution of specialty products across Southeast Asia.

At the moment, many leading historical groups of pharmaceutical companies in Taiwan seem to be shifting their strategic focus to enter the new drug development area and/or increase their international footprint, what is the vision driving the development of Orient EuroPharma?

I set up Orient Europharma (OEP) in 1982 as a distributor for France's Rhône-Poulenc. Given that for the first few years we were successful, I started to diversify the company's client base, entering talks with Hoechst and Elan. However, the strategy changed when these big European pharmaceutical giants began merging with one another, and we started to license in products from European companies such as Italy-headquartered Chiesi and Recordati or France's Pierre Fabre, for whom we are the regional distributor serving Singapore, Malaysia, Hong Kong, and Taiwan, but also partnering with Almirall and Pfizer – among many others.

In this regard, consolidating and expanding our distribution footprint throughout Southeast Asia remains one of our current priorities. In addition to our existing subsidiaries in Singapore, Malaysia, Hong Kong, the Philippines, and China (in Shanghai and Guangdong), we plan to enter Thailand and Vietnam in 2017 as well as further increasing our footprint in Indonesia, where we already hold a company. In the meantime, we continue to strengthen our product portfolio, which includes primary care and specialty pharmaceutical products (notably oncology drugs), nutrition, cosmetic and other health-related products. Orient EuroPharma notably owns a leading brand of goat milk powder, Karihome®, which we have been successfully marketing in various international markets. Although we hold a diversified portfolio and work with various partners, we are a very focused company which essentially favors a specialty, niche product approach when it comes to enriching its portfolio.

For example, in 2016 we became the first Asia-based company to sign a cooperation agreement with US-headquartered Second Sight Medical Products to obtain the exclusive distribution rights for their Argus II® Retinal Prosthesis, a breakthrough implantable bionic eye technology for patients suffering from retinitis pigmentosa. As a matter of fact, on April 13 2017, Argus® II Retinal Prosthesis has been implanted in the first patient in Asia thanks to this exclusive distribution partnership and the charitable support from the Hong-Lu Foundation in Taiwan. In 2016, we also entered into an exclusive distribution agreement with Taiwan-based biopharmaceutical company Mycenax, with the objective to explore the Southeast Asian market for TuNEX®, Taiwan’s first ever biosimilar product. In a region where affordability remains evermore critical than in Europe or the US, I definitely believe that this product holds great growth prospects.

As a result, my vision for Orient EuroPharma is to keep this two-fold focus at the core of our development strategy: on one hand, further attracting new, innovative and/or difficult-to-make products, and – in the meantime – concentrating our resources allocation and expansion plans in Southeast Asia, where we are already regarded as a partner of choice by leading companies globally.

Nevertheless, distribution is a tricky job: if you are unsuccessful in marketing a particular product, the licensor is disappointed in the work you do – if you are successful, then the company considers entering the market by itself! As my overarching objective is to ensure Orient EuroPharma will continue to thrive over the next decades, we have been significantly enriching our business model over the past decade.

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How has this diversification been impacting the activities and structure of the group?

In parallel to our trading activities, which have been OEP's main growth drivers over the past 35 years, we set up in 2008 OEP's manufacturing and drug development subsidiary, OrientPHARMA Co., Ltd (OP), which has had a number of milestones.

On the manufacturing side, the construction of OP's production plant was completed in 2010, and, by 2011, we received PIC/S GMP certification. More importantly, our plant is now certified by the US FDA, and Japan MHLW– a key achievement in our company's history and a critical milestone for our future development, as we can now strategically focus on developing products that can be submitted to FDA immediately. In the meantime, this world-class manufacturing arm stands as a particularly attractive asset for international companies who have strong R&D capacities but less developed manufacturing capabilities, putting us in the position to develop comprehensive partnerships encompassing CMO services.

Looking at our generics exports, we already have two products sold in the US market. Carisoprodol, a muscle relaxer, was approved by US FDA in 2014, and miglitol, an oral anti-diabetic drug, was approved in 2015. In addition, we received our first Paragraph IV product approval in early 2017 for an in-house developed anti-hyperlipidemia product, which truly marked a great step into the huge and challenging US market and proudly stands as another historical milestone for our company.

In terms of product development, we notably focus on CNS drugs, including anti-psychotics and drugs for treating Alzheimer's and Parkinson's disease. We especially aim to develop new products which are eligible to US FDA's 505(b)(2) pathway. In this regard, OP already owns three unique and innovative drug development technology platforms, Multi-Phasic Release Technology (MPRT), Multi-Day Transdermal Drug Delivery (MTDD), and Multi-Layered Pulsatile Release Technology (MLPT) which will contribute to rapidly enrich OP's product portfolio with new dosage forms, new formulations, new indications, and new drug combinations in our target areas. As I still perceive NCE development as too risky for a company of our size and experience, 505 (b)(2) products offer the advantage to reduce our risk exposure while being more rewarding than generics products, where price competition would prevent us from generating the profits needed to enhance the long-term growth of the company.

In the meantime, we are increasingly collaborating with US, EU, and Japan-based companies for new product development. In 2012, we expanded our R&D capabilities in the cancer drug area and signed an agreement with Japan's NanoCarrier for the development of micelplatin, an anti-pancreatic drug, on which we have been working since its phase I trial. As part of our agreement

with our Japanese partner, we also started the construction of a dedicated injectable plant in Taiwan in 2014. We expect its construction to be completed before the end of 2017, while we will also look for US FDA certification, providing OEP with a two-arm manufacturing capacity encompassing both oral dosage forms and cytotoxic oncology injection products. We are also conducting a phase III clinical trial in Taiwan, Singapore, Malaysia and the Philippines for multikine, an immunotherapy drug for head and neck cancer, developed with U.S.-based Cel- Sci.

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In the grand scheme of things, our partnership strategy is absolutely critical to our ambition to climb up the value chain and engage in the development of higher-value products. If we identify the development of a product would be too long or too risky for us, we then want to partner with small and mid-size international companies that will be eager to leverage our manufacturing and distribution expertise and share development risks and rewards.

Overall, we currently hold five products undergoing phase III clinical trials, and I expect our portfolio to evolve significantly over the upcoming years. In the meantime, I foresee these products' launches could bring our group's revenues from USD 150 million today to USD 300 million within the next five years.

Considering you started developing 505(b)(2) products only recently, why should these international companies collaborate with Orient EuroPharma?

When it comes to such a long and risky process as drug development, holding a partner that is utterly committed to this endeavor is absolutely paramount. OEP perceives the development of high-quality 505(b)(2) products as the future of our company; we are then ready to invest substantial resources into this field, although these products' development is more expensive than for generics. We hold the financial means, the technology platforms, and the manufacturing capacity to efficiently bring new 505 (b)(2) products onto the global market – and I believe this specificity stands as a true competitive advantage, even from a global standpoint.

In the meantime, we are particularly flexible when it comes to designing the shape these partnerships should take. We would for instance be ready to leave to our partner the commercial rights for key markets, including the EU, China, or Japan; the most important aspect to us being to leverage our marketing and sales network in Southeast Asia.

I think our financial commitment and this commercial flexibility make us a very appealing partner in the eyes of most small and midsize companies globally. These companies, especially from

Europe, the US, or Japan, are typically not interested in marketing their products by themselves in Southeast Asia, as the region's market is utterly fragmented with a wide variety of challenging countries displaying different languages, business cultures, and regulations.

What are the main challenges that come with the diversification of the company's activities?

While we have established OEP as the distribution partner of choice of international companies in Southeast Asia, drug development remains a relatively new field to our company.

Developing our capacity in this area, especially for 505(b)(2) products, required to efficiently build a competitive R&D capacity over a rather short period of time. On the other hand, drug development implies to carefully align your investment plan with development and regulatory timelines, while – overall – you have to ensure the company holds the financial means to bring these products onto the market, be it by itself or through partnerships.

To accelerate this transition and increase our chances of success, I have been instilling a true international thinking to OEP, which I see as the only way to be competitive in this global field. Seasoned executives coming from Big Pharma companies have now joined our company's board, while, at the R&D and middle management levels, we have been hiring talented professionals directly from US.

Nevertheless, the strengthening of our company's R&D and strategic capacities is still on going, and I want to see more international experts joining our company in the upcoming years, with a special focus on the CNS and diabetes fields.

Taiwan holds a relatively significant number of biotech startups that have been successfully developing 505 (b)(2) products thanks to in-house developed technology platforms. Given your ambitions in this field, would you consider triggering an M&A approach to ramp up the broadening of your portfolio?

We are indeed particularly interested in such opportunities, but it is easier said than done. I feel most CEOs of Taiwanese biotech companies are mostly interested in ultimately selling their companies to Big Pharma companies, while the price they ask for their companies is usually very high.

In the grand scheme of things, we are also considering acquisition opportunities in other advanced Asian markets, such as South Korea, as well as in Europe and the US, but I expect we will heighten our ambitions on this side as our revenues keep on increasing thanks to new product launches.

What would you be your final message to our international readers?

Over the past 35 years, I have been dedicating my energy to build a company that is now regarded as an honest, trustworthy, and reliable partner to work with – and our company's core values ("Integrity", "United We Achieve", and "Be Remarkable") will continue to frame the way we conduct our business on a daily basis.

Partnership truly is at the core of our company's growth strategy and Orient EuroPharma already stands – in many ways – as the integrated partner of choice of international companies. Whether it relates to our historical trading business and our appealing expertise in Southeast Asia, to our 505(b)(2) ambitions and our eagerness to partner with leading international companies, or to CMO activities leveraging our US FDA, Taiwan FDA and Japan MHLW approved manufacturing capabilities, we will continue to tirelessly improve our own capacity to make the most of these crucial assets and build win-win relationships with our existing and upcoming partners.

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