Interview: Wang Yu Pei – General Manager, Nang Kuang Pharmaceutical, Taiwan

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Wang Yu Pei, general manager of Nang Kuang Pharmaceutical, Taiwan's indisputable market leader for injectable products, provides insights into the global ambitions of the company as Nang Kuang is about to bring its first injectable into the US market and is also looking for Europe-based partners to distribute its high-quality products, which have been successfully exported to Japan for more than two decades already.

Could you introduce Nang Kuang Pharmaceutical to our international readers?

Nang Kuang was founded in 1963 and has – over the course of the past five decades – established itself as a leading pharmaceutical company in Taiwan and in the region, thanks to our unrivalled expertise in the injectable field. I joined the company in 1970, when Nang Kuang only held twenty employees and our revenues did not exceed NTD 3 million (less than USD 100,000). Now, Nang Kuang is a publicly listed company with annual sales close to NTD 2 billion (around USD 50 million) and holding around 600 employees.

Our portfolio encompasses large-volume parenteral (LVP; PP plastic bag) and aseptic parenteral products (ampoule, vial), lyophilized injections, prefilled syringes, pre-mixed IV infusion bags, tablets, capsule, and oral suspensions. Our enduring success takes its roots into the pioneering approach that our company has been historically following: for example, in 1996, we became the first company in Taiwan and in Asia to use PP-composite plastic bags (instead of PVC bags), while

we were also the first injectable company in Asia to adopt a large-scale, fully automatized production line in order to reduce human and external contamination. We now proudly stand out as a Top Eight aseptic parenteral manufacturing company in the region and the incontestable market leader in Taiwan, with a market share of over 30 percent.

Over the past few years, we have been mainly focusing on the production of ready-to-use products, such as prefilled syringes and premixed IV infusion bags, while most of our products target critical and severe diseases including oncology as well as prevention-oriented treatments. Nang Kuang's competitive advantage is our irreproachable ability to provide local and international customers with a timely and extremely safe production of easy-to-use and high-quality injectable products.

Nevertheless, we do not plan to rest on our laurels and are very focused on nurturing the long-term growth of the company. In 2015, we displayed a 26 percent growth rate in comparison to 2014, which slightly slowed down to a single-digit growth rate in 2016. Nevertheless, for 2017, we plan to renew with our historical double-digit growth rates, thanks to a rapid increase of our overseas revenues, especially coming from the US market.

Talking about the US market, when do you expect to launch Nangkuang's Linezolid, an in-house developed antibiotic product used for the treatment of infections caused by Gram-positive bacteria that are resistant to other antibiotics, which received US FDA approval in December 2016?

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We expect to launch this important product in April 2017. We already found a strong local distributor for linezolid, and we plan to further expand this partnership as other Nang Kuang's products will soon enter the US market. As a matter of fact, linezolid stands as the first among many upcoming products that we will be launching in the US within the next two years, showcasing the indisputable strengthening of our company's international ambitions. Overall, we hold five products ready to be launched in the US: we already received US FDA market approval for Linezolid, while the four other products should receive market approval in the upcoming months.

For a company focused on injectable products that already is market leader in its domestic market, increasing your international footprint is absolutely crucial to sustain the long-term growth of Nang Kuang. How would you describe the company's international strategy?

Beside the five products that we will soon launch in the US, we are now looking at binding local partnerships with well-established distributors in Europe, a market that is still new to us. Considering that regulations and marketing strategies vary a lot from one European country to another, we strive to approach European countries individually and to find country-specific partners that will be fully able to maximize our products' commercial potential. In the grand scheme of things, distributors will allow us to bring our products onto the different European markets we envision, but – in the long run – we plan to develop a direct sales presence in these countries and build a more integrated, international marketing presence spanning key markets in Europe.

In China, we recently saw a lot of changes happening on the regulatory side, and I consider that regulations and IP protection have been improving over the past few years. We are now ready to apply for CFDA market approval, but I do not want to rush our market entry into this challenging and strategic market, as regulatory requirements may evolve again in the upcoming months. In this regard, we prefer to ensure that the regulatory context in China truly stabilizes before moving forward.

What are Nang Kuang's competitive advantages that should appeal to European distributors?

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Injectable products indisputably are among the most challenging treatments to manufacture. As a result, holding a long-standing expertise in this field stands as a critical asset. For example, Nang Kuang was the first company in Asia to venture into the production of PP plastic bags, and now, we boast more than twenty years of experience in this product category.

Nang Kuang has also invested tremendous resources in both its R&D and manufacturing capacities, to ensure we remain at the forefront of the international industry. Our overall manufacturing capacity received cGMP and PIC/S GMP certifications and was successfully and repeatedly inspected by both the US FDA and Japan's PMDA. We were the first company in Taiwan to build an entire facility dedicated to the manufacturing of oncology products and holding an isolator – a decontaminated sterile unit that provides uncompromised, continuous isolation from the external environment. I think we are still the only company in Taiwan holding such a state-of-the art level of manufacturing equipment.

Finally, Nang Kuang has already gained the trust of both US and Japanese regulators and commercial partners, which are among the most stringent in the world – I am confident this recognition will contribute to convince European partners to choose our products!

Considering that Nang Kuang Pharmaceutical has been successfully exporting oncology injectable products to the Japanese market for more than twenty years ago, why did you wait until very recently to enter the US market?

When we truly started to internationalize our activities more than 20 years ago, Taiwan's cultural ties with Japan and our knowledge of the Japanese regulatory context made it easier for us to first concentrate our efforts on this market – despite Japan's regulatory requirements being of course as constraining as in the US.

Nevertheless, over the course of the past decade, key executives having studied and/or work in the US joined our company, such as Penchung Chen, our R&D Director, which prompted us to steadily consider broadening the scope of our international ambitions. In 2017, entering the US market has truly become a reality for Nang Kuang, and I am utterly convinced we will soon be able to display similar success in Europe.

President Tsai has established Taiwan's biotech and pharmaceutical sectors as a key pillar of Taiwan's new economic model. Do you feel that historical, well-established companies like Nang Kuang are fully considered in the government's ambition to make Taiwan the pharmaceutical hub in the region?

We are pleased to see that President Tsai is extremely committed to making Taiwan's pharmaceutical and biotech sectors the cornerstone of our country's long-term economic growth. Nevertheless, we feel that government is investing all its resources – and they are substantial – to drive the growth of biotech start-up companies, which – for most of them – will not generate any revenues before many years, if they ever do so one day. In the meantime, companies like Nang Kuang and other generics manufacturers already pay taxes, increase their workforce, and take on the challenge to internationalize their activities – but receive far less government support.

In the meantime, we see that most emerging Taiwanese biopharmaceutical companies are so far essentially focused on R&D activities and do not hold the manufacturing capacity to produce their innovative treatments, which are – for most of them – injectable products. Given this relationship, it is then easy to understand why government support should also target domestic pharmaceutical manufacturers. Allocating more resources to well-established pharmaceutical manufacturers in Taiwan is absolutely essential if we do not want to weaken the manufacturing part of our country's value chain and leave our emerging biotech companies with no choice but to partner with international suppliers and manufacturers in the mid term.

Taiwan’s pharma and biotech sectors should be considered as a true and complete ecosystem, and pharma manufacturing companies definitely hold both a critical role to play and a crucial importance in boosting the development of this ecosystem.

How can we expect Nang Kuang’s activities to evolve in the upcoming years?

Nang Kuang’s key competitive advantage is and remains its outstanding capacity to manufacture complex injectable products and meet the most exigent quality standards internationally. In the short-term, we may increase our contract manufacturing activities, notably for the manufacturing of clinical batches and new drugs. In the meantime, we will leverage our industry expertise and unique manufacturing capacity to bring an increasing number of proprietary formulations onto international markets.

We notably hold in our R&D pipeline a sustained-release injectable drug, which indisputably stands as one the most complex drug delivery systems existing, and we plan to launch this challenging product onto the global market within the next five years.

In the long term, we also consider the opportunity to close strategic partnerships with leading biopharmaceutical companies, and, eventually, to invest in some thriving Taiwanese biotech companies.

Nevertheless, whatever new activities that we may venture into, we will never compromise our company’s key strengths and assets that have led to establish Nang Kuang as the partner of choice globally for injectable manufacturing. In our field of expertise we are the market leader in Taiwan with more than fifty years of experience and already display a very successful track records in the Japanese market – we are now ready to move forward on our international ambitions and replicate such successes in the US and in Europe.

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