Interview: Chuan-Der Huang Ph.D – President & CEO, KriSan Biotech, Taiwan

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Chuan-Der Huang, founder, president, and CEO of KriSan Biotech, a recently established Taiwan-based service provider focused on new drug process and analytical R&D for small molecules and peptides from Pre-clinical (IND) to Phase II clinical trial, provides insights into the company's unique positioning in Taiwan's new drug development value chain, as well as KriSan's overarching mission to operate as a crucial incubation center boosting the R&D efforts of local and international companies.

You founded KriSan Biotech in 2015, after having honed your industry expertise for more than 16 years, especially at one of Taiwan's leading companies, the API manufacturer ScinoPharm, where you were one of the company's directors. What was the market opportunity that prompted you to set up KriSan Biotech?

As you know, Taiwan holds particularly vibrant domestic pharmaceutical and biotech industries, comprising an impressive and continuously increasing number of companies involved in research and development activities. Nevertheless, I noticed that – for many services that are however crucial in the new drug development process – these local companies could not rely on world-class, locally based service providers. For example, our country holds at least five API-focused companies; nevertheless, most of them are concentrating their efforts on large-scale API production.

Hence, our local pharmaceutical and biotech companies historically had to look overseas to find API specialists focused on the early-stage R&D process and the manufacturing of clinical trial batches – most of the time in China or in the US. Nevertheless, partnering with a US-based service provider is usually more costly than with a local company, without even mentioning the time difference and cultural difficulties that can affect the delivery of such partnerships. In the meantime, we see that IP-related issues have somehow tarnished the reputation of China-based service providers.

In this context, the market opportunity driving the creation of KriSan Biotech is almost obvious: a Taiwan-based company founded by industry experts that can provide the local the industry with reliable, high quality chemistry process and analytical R&D services at a favorable cost. KriSan Biotech now offers a vast array of API custom synthesis services, spanning from process and analytical R&D for small molecules and peptides from Pre-clinical to Phase II clinical trial, CGMP manufacturing of API for clinical trials (few grams to kilograms scale), stability test in accordance to ICH guidelines and CMC preparation for IND filing.

Considering this lack of locally based service providers, how did you ensure that Krisan Biotech would hold the industry expertise required to meet your customers' expectations?

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In addition to myself, most of KriSan's employees have worked among Taiwan's leading companies, which provided them with an unrivalled expertise in this field. As a matter of fact, although KriSan stands as a dynamic company with rather young employees, all of them already boast more than ten years of industry experience at the leading companies in the sector.

I personally supervised the development of more than 100 New Chemical Entities (NCE) over the course of my career, with five of them having already reached the market and five others being currently in phase III. Beside this R&D expertise, most of KriSan's teams also had the opportunity to directly counsel and guide ScinoPharm's external clients, having for example contributed to already four FDA NDA approvals prior to joining KriSan.

Leveraging these R&D and consulting experiences in the API field, KriSan's customers can now benefit from this expertise through a service provider that is essentially focused on the early phase of the drug development stage. Given this specific focus (from pre-IND to phase-II), KriSan truly strives to operate as an incubation center, optimally bringing customers' products from the pre-clinical stage to a more advanced development phase, where we can ensure a smooth transition with a larger API manufacturer.

A year after it started its operations, KriSan already has 38 employees. What have been the main milestones of the company since its creation?

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Established in September 2015 in Tainan's Southern Science Park, KriSan received a first round of funding in October 2015 that allowed us to gather an initial capitalization of around NTD 200 million (around USD 6.6 million). Our company's process and analytical lab started its operations in March 2016, a few months before we opened our 30L and 50L API manufacturing facilities in August of the same year. In 2016, we also successfully passed inspections from three different customers, respectively coming from Europe, the US, and Taiwan.

Only a few months after we started our operations, we are already working with 16 different customers, including two customers that are based in the US and in Europe. Having been able to earn the trust of international customers after only a year in operations truly proves that our unique positioning – combining Asian cost-efficiency with Western knowhow – can also be extremely appealing on the international stage.

In the meantime, we have signed a referral agreement with two local API pharmaceutical companies through which the latter refers to us some of its customers for the early-stage R&D activities that they cannot conduct. In turn, we will also refer back to them our customers as soon as they reach a later stage of their drug development process. As a result, this agreement allows us to provide our customers with a comprehensive scope of services, combining KriSan's expertise for early stage development with the two companies' leadership for large scale manufacturing services, without having to upgrade the scale of our own laboratories or manufacturing facilities.

Taiwan-based companies make up more than 90 percent of our customer pool, and our first and foremost priority at the moment will be to service our domestic market's needs and contribute to foster the development of the local new drug development industry. Despite the large and increasing demand for our services, we remain a recently founded company with limited resources. As a result, remaining essentially focused on the Taiwanese market for the moment will allow us to gain the credibility we still need to earn, without losing sight of our quality standards.

Once we will have consolidated our footprint in Taiwan, we plan to expand our focus to other regional, technically advanced markets, such as Japan, where we could leverage cultural and geographical proximities to rapidly increase our market share. Although expanding our customer basis in the US and Europe does not stand as a priority in the short term, we are however ready to welcome any new international customers, by leveraging for example our employees or investors'

overseas networks.

Taiwan’s biotech industry is often considered as one of the most promising in the world. From a service provider perspective, what is your assessment of Taiwan’s biotech value chain as a whole?

Taiwan has undoubtedly managed to build a dynamic and increasingly successful biotech industry, comprising companies headed by brilliant and experienced experts with international exposure. In the meantime, our country’s biotech-focused stock market is probably second only to the US. Nevertheless, our government should not only concentrate its efforts on ensuring that our companies can easily raise funds – especially since the continuous shift of Taiwanese investors’ resources from the semiconductor to the biotech field has been providing most of these companies with easy access to substantial funding.

To the contrary of other advanced biotech eco-systems around the world, Taiwan still lacks of comprehensive, fully-fletched hubs, gathering within a close perimeter the entire biotech value chain, from emerging drug development companies to world-class service providers and cutting-edge medical and research capacities. As a result, these well-funded, publicly-traded biotech companies still struggle to find service providers aligned with their own standards, highlighting that beside the undeniable quality of our biotech companies, Taiwan’s biotech value chain still needs to be substantially strengthened, and KriSan Biotech strives to contribute to the fulfilling of this objective.

After such a promising start, what are your strategic priorities to further propel the growth of the company over the upcoming years?

First, I want to ensure KriSan delivers on its promises. As I just mentioned, we are already working with 16 customers, encompassing both local and international companies. In this regard, our strategic priority will be to ensure we can honor our commitment toward these partners – on time – and by displaying the highest quality standards.

These customers now rely on our delivery to move their clinical trials forward, which means that the quality of our delivery could have a significant impact on their R&D timelines and these companies’ growth overall. As a recently established service provider, our ability to meet our customers’ expectations will play a critical role in building the company’s reputation in the Taiwanese market. In this regard, we have been working since the company’s conception on establishing the hardware and software systems that would allow KriSan to remain as time-efficient as possible, even as the number of our customers keeps on increasing.

Many biotech companies have leveraged Taiwan's vibrant stock market to accelerate their growth; to what extent do you consider becoming a publicly-listed company in the near future?

An IPO undoubtedly stands as growth option that I consider with interest. Nevertheless, our first objective will be to break even, which – according to our 2o17 projections – stands as an objective will could be able to reach over the course of the year. As a service provider, our investment needs are less important than for drug development companies, whose R&D activities are particularly investment demanding. Over our first year of operations, our revenues already overcame the USD-1 million mark, and we expect them to grow more than 100 percent in 2017, as our target is to reach USD2.5 million.

As part of our business model, we are eligible to receive commissions every time one of our customer's products eventually reach the market. As soon as we will receive these additional incomes, we plan to start investing in early stage new drug development companies, which usually struggle to draw investors' interest. In the long term, these strategic investments in early stage products could allow us to tremendously increase our financial assets and nurture the further development of the company. Nevertheless, we do not expect to get into product co-development strictly speaking and will truly remain a service provider focused on providing our expertise to our customers.

In the grand scheme of things, my objective is to ensure that KriSan establishes itself as a technically reliable service provider operating as an incubation center, efficiently bringing our customers' products from the early stage of their development pathway to the production and commercialization phases, on time, and with the highest quality of services and guidance possible.

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