Interview: CS Hsu Ph.D. – President, Innopharmax, Taiwan

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Ten years after its creation in 2005, InnoPharmax was ranked seventh fastest growing technology company in Taiwan in Deloitte's

"Technology Fast 500 Asia Pacific" annual ranking*. CS Hsu, founder and president of InnoPharmax, introduces the company's most fundamental asset – OralPAS®, its unique technology platform, and documents the promising development options he envisions for the company.*

You founded InnoPharmax in 2005 after having developed extensive industry experience among local and international biopharmaceutical companies. What has been the vision driving the creation and development of the company over the past decade?

The true core of our company is our in-house developed technology platform, OralPAS®, a self-microemulsifying drug delivery system which allows the transformation of an existing, non-oral product (for example an injectable) into an oral dosage. Besides oral dosages being the most convenient drug form for both patients and healthcare professionals, OralPAS® technology also allows for an increase in the solubility and dissolution of the drug and its resistance to enzyme degradation, while also enhancing absorption through structural or fluidity changes in the intestinal membrane.

As a consequence, our first objective when embarking on its new adventure was to design, develop and strengthen the technology platform we envisioned. OralPAS® and our technology capacity

overall has now truly become InnoPharmax's core business, and we clearly position ourselves as a technology-based biotech company rather than being focused on a specific therapeutic area.

The rapid development of our company probably lies in the fact that my partner Ms. Hao (who is the co-founder) and I hold complementary competences when it comes to developing new formulations and combinations and bring them to the global market. While she is notably taking care of the R&D activities of the company, I am handling the clinical and regulatory aspects while nurturing the progress of our international businesses – in addition to my responsibilities as president.

Based on our game-changing technology platform, InnoPharmax has been simultaneously advancing both long-term and secondary projects – the latter aiming to provide the company with the resources we need to develop our most promising, long-term products. In the meantime, these secondary projects also provide us with the incomes we need to satisfy our investors and continuously invest in the development of our technology platform. In this regard, OralPAS® has been drawing the interest of a rapidly-growing number of international pharmaceutical companies over the past years, essentially from China or India but also from North America and Europe, and we are now involved in several commercial partnerships all around the world.

In 2015, InnoPharmax was ranked seventh fastest growing technology company in Taiwan in the *"Deloitte's Technology Fast 500 Asia Pacific ranking"* by displaying an impressive year-on-year growth rate of 519 percent. As CEO, how do you ensure the company will be able to display similar growth rates in the upcoming years?

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We felt particularly honored to be recognized as one of the fastest growing technology companies in the Asia Pacific region – all industries included. Fundamentally, our business model is very different from many other Taiwan-based pharmaceutical companies: we do not license-in early-stage products or rely on externally developed technologies. To the contrary, our teams have developed OralPAS® from scratch, an effort that has clearly paid off as we now hold many patents in various international markets, covering not only the commercial rights of our products but also their APIs. Nevertheless, 2016 was a pivotal year for our company. Although we first wanted to trigger another phase of rapid growth to ensure our sales would soar at a similar pace as in 2015, we decided to postpone this sales boost to concentrate our efforts on consolidating our company's competitive advantage.

Ten years ago, we started to collaborate with a local API manufacturer to develop an exclusive active ingredient used for our magnetic resonance imaging (MRI) contract agents, a group of products absolutely crucial to our US sales since they were granted an US New Drug Application (NDA) in 2014. As you know, APIs are determinant to guarantee patent registration and market approval, which explains why we ensured this manufacturer would exclusively produce this API for our company. Unfortunately, a couple of years ago, this manufacturer had a different view in business which could have endangered our API supply in the mid-term. In order to secure our business model, we then decided in 2016 to become the new majority shareholder of this API manufacturer, co-investing alongside with our own major shareholder to now hold 90 percent of its capital.

This investment truly is a long-term decision. Some of the most important products in our R&D pipeline will also rely on the APIs with similar synthetic process, and we will soon be able to vertically optimize the production of an even larger number of our products – and above all more closely control our product costs and improve our margins. Over the second half of 2016 we have been gradually taking over this new part of our value chain, while we now expect that, by mid-2017, we will be fully operational and integrated and ready to trigger the new growth phase we had initially set up for 2016.

As president of the company, what is your strategic priority for the upcoming years?

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Our fundamental priority is to advance the clinical development of our long-term projects and bring them to the global market. We want to build a true success story and showcase to the world that InnoPharmax can successfully develop a new drug, complying with the requirements of the US FDA's 505(b)(2) NDA *(one of three U.S. FDA drug approval pathways, which avoid unnecessary duplication of studies already performed on a previously approved drug by to relying on data not developed by the NDA applicant, e.d.).*

We have already brought to the global market a generic product through a licensing partnership with an international company. We now want to replicate such success outside of the generics field and prove that InnoPharmax is ready to fully leverage its technology capacity for the development of new products, in an increasing number of therapeutic areas.

In January 2016, InnoPharmax received US FDA Orphan Drug Designation for Gemcitabine Oral in the treatment of Cholangiocarcinoma. When do you expect to start phase II clinical trial for this product?

We are currently working with our partner CRO to design and develop the clinical protocol of the phase II. We assume that once we will have achieved the primary endpoint of this clinical study, we will be able to start designing the protocol of the phase III while opening negotiations with the US FDA to receive fast-track designation.

In the US, there is so far no approved medicine for the treatment of Chlangiocarcinoma, beside an injectable available under NCCN guidelines. Nevertheless, after a 6-month chemotherapy, it is physically difficult for patients to handle the frequent injections as prescribed. If we manage to bring Gemcitabine Oral to the market, patients will then be able to live longer and less painful side effects, as our oral treatment will be more convenient and lightly dosed than the aforementioned injectable.

Gemcitabine Oral however is not the most advanced product in our R&D pipeline: D07001, our chemotherapy agent, has already initiated a phase II clinical trial in the US; while C08001, our heart failure treatment, is about to end its pivotal study in 2017 and get ready to file NDA to the US FDA.

Considering these treatments' development is steadily coming to an end, how do you plan to bring them to the market?

For a company of our size, promoting an oncology product like D07001 on the American and EU markets necessarily requires partnering with an extremely resourceful ally. InnoPharmax cannot market by itself a treatment in such a competitive therapeutic area, be it in the US or in the EU. For this product, we are then looking for a business partner which holds a long-standing experience in the oncology field, but also the resources, network and marketing capacity to fully leverage our products' commercial potential.

Actually, this commercial approach also applies to our orphan drug treatment. Cholangiocarcinoma is not a rare genetic disease, but a form of cancer that is composed of mutated epithelial cells that originate in the bile ducts and drain bile from the liver into the small intestine. As a result, there is no established focus groups or national registries that could ease patient targeting, and holding robust relationships with oncologists is the only way to raise awareness around our treatment. By the time we would have built the sales and marketing network to cover the US territory, our patent would have probably already expired – without mentioning the heavy investment needed to build such an important in-house sales force. We also need to take into account that other biopharmaceutical companies may soon bring to the market a new option in this therapeutic area. This product could sooner or later replace our treatment, so we cannot afford to loose any time in

our go-to-market strategy.

After having assessed the funds we need to bring our aforementioned treatments to the NDA stage, we found out that we actually hold the financial capacity to complete their development by ourselves. As a consequence, we legitimately questioned the necessity to close a licensing agreement at this R&D stage, especially considering that the efficacy of these products' chemical entities has already been approved (in their injectable form) by the main regulatory agencies of the world since a long time. Finally, as these new products are not new chemical entities, we will not need to run several multi-center phase II and III clinical trials before receiving market approval, but only a pivotal study. Overall, our risk exposure would be extremely limited.

Nevertheless, my priority is to close these license-out partnerships as soon as possible, as I do not want to lose the focus of our company: we are above all a technology-based biotech – not a company bounded to its products. By licensing-out these products, we could then shift our technology capacity and allocate these new financial resources to our next projects. As a result, we are currently discussing the US and EU market rights with a couple of very qualified partners, but nothing has been yet officially signed, although we hope this negotiation phase will soon reach a positive end.

Talking about resource allocation, what are the most promising projects that could soon benefit from the additional incomes you may receive?

We hold in our R&D pipeline a licensed-in, non-invasive glucose detector that we expect to bring to the market in the upcoming years. We also have a protein agent for metabolic disorders, N11005, which currently is at the preclinical stage. By leveraging OralPAS®, we could turn this protein agent into oral insulin and combine it with our non-invasive glucose detector. If we manage to bring these two products on the market and build the synergies we have in mind, the market opportunities for our company would then be absolutely mind-blowing.

Overall, our long-term objective also is to further develop our unique technology platform. Given the physiological impact of our products, the pharmaceutical industry remains more conservative than the IT sector in terms of risk exposure, which explains why our innovation cycles are substantially longer. Nevertheless, as a technology-based biopharmaceutical company, we cannot afford to fall behind the latest innovation trends.

In the grand scheme of things, InnoPharmax's philosophy is to develop new drugs through the most innovative ways possible, in order to maximize the biological benefits these treatments can offer, from both clinical and cost-effectiveness standpoints. With OralPAS®, we already hold the

technology platform we need to fulfill this fundamental objective, while our teams are fully committed to broaden this two-fold positive impact, for the sake of our patients and the sustainability of healthcare systems around the world.

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