Interview: Terry Lin – General Manager & Freia Wei – Director International Business, UniPharma, Taiwan



"In the grand scheme of things, UniPharma's core approach is to offer innovative answers to unmet medical needs arising from Taiwanese patients"

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Terry Lin, general manager, and Freia Wei, director for international business at UniPharma, on the company's move from specialty distribution to drug development and diagnostic products. With an upcoming IPO, UniPharma is considering both organic and inorganic development opportunities to further nurture its geographical expansion.

Being one of the best-established specialty distributors in Taiwan, UniPharma has been continuously broadening the scope of its operations since 2010. Where does the company stand now and what is its positioning among the Taiwanese and international healthcare industries?

Terry Lin (TL): In the grand scheme of things, UniPharma's core approach is to offer innovative answers to unmet medical needs arising from Taiwanese patients, while in the meantime we have been tremendously strengthening our presence on the international stage. As part of our distribution activities, we then remain particularly interested in all pharmaceutical and healthcare products that are not yet available in Taiwan.

Nevertheless, UniPharma's business model has indeed been greatly evolving from a distribution-focused approach to a broader structure encompassing four business units. The first one relates to the distribution of specialty drugs for use in operation and emergency rooms; the second relates to our in-vitro diagnostic (IVD) kits for the detection of more than 13 cancers (Onko-sure®), while our

third business unit comprises our radiofrequency ablation medical devices designed to help physicians treating cancer. Finally, our fourth and last business unit relates to the diagnostic services we can now offer through our recently established in-house medical laboratory, which was set up in 2016.

The establishment of an in-house laboratory indisputably stands as a crucial milestone in the growth trajectory of the company. What motivated you to invest in the development of this new diagnostic facility?

Freia Wei (FW): This laboratory indeed proves that UniPharma is no longer solely a specialty distributor, while we recently applied to receive ISO/IEC 17025:2005 and ISO15189:2012 certifications for this testing laboratory. As a specialty distributor, UniPharma has been closely partnering with Taiwanese physicians for a long time already, initially focusing on the multiple sclerosis field. We hence noticed that a large number of highly-specialized in-vitro diagnostic services were still unavailable in Taiwan, while on the other hand the number of companies performing some diagnostic testing was so limited that it generated unsatisfactory waiting time for patients. We then decided to establish our own medical laboratory to provide both physicians and Taiwanese patients with a larger access to the diagnostic services they need.

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TL: Thanks to this medical laboratory, we are also developing our own testing methodology and products to diagnose life-threatening diseases. In this regard, we truly want to go beyond offering diagnostic services that are unavailable in Taiwan, as UniPharma has been working with academic institutions as well as with clinical research centers of Cathy Medical Research Institute to jointly develop ground breaking, new diagnostic products and services.

As part of this R&D strategy, what kind of diagnostic products are you developing?

TL: We are for example currently developing a diagnostic test for anti-NMDA receptor encephalitis. This acute form of encephalitis is caused by an autoimmune reaction that is potentially lethal, although it nonetheless holds a high probability for recovery (without neurologic sequelae) if it is properly diagnosed. Nevertheless, patients often go through dramatic life experiences before being diagnosed, as described by Susannah Cahalan in her 2012 bestselling autobiography, *Brain on Fire: My Month of Madness.* By detailing Ms. Cahalan’s struggle with this rare autoimmune disease, this book contributed to shed light on the crucial need to develop better diagnostic capacity in this field and prevent patients from being wrongly diagnosed as suffering from psychiatric troubles – although we had already started developing this diagnostic product before the release of this

autobiography.

We are still working on the pre-clinical development of this diagnostic test, and I foresee that we would need two more years to complete the design of our final prototype and obtain all the certifications we need to bring it to international markets. Overall, our R&D strategy in terms of diagnostic tests is to focus on underserved, life-threatening autoimmune diseases.

Another recent milestone for the company relates to the clinical development of its first drug, an oral dosage form of an antidote targeting methanol and glycol poisoning. When do you expect this product to be available?

TL: The market potential for this product is absolutely huge in Asia, where cases of severe illness (including permanent blindness) and death have been increasingly reported following over consumption of alcohol. As most of the current treatments are only available through injectable forms, which are not particularly convenient for both patients and healthcare professionals, we then decided to develop an oral dosage of an existing treatment.

This product is about to complete its clinical development and will be eligible for a US FDA 505 (b)(2) filling. We then expect to receive TFDA market approval by the end of 2017, before looking to get market authorizations in other strategic markets.

FW: With 32 employees, UniPharma remains a relatively small company. We then need to be extremely cautious regarding the number of international projects we decide to pursue. As a result, we are currently looking for strategic partners which would handle the registration and launch of this product in key markets in the region, namely China, South Korea and Japan.

TL: More than 50 percent of the East Asian population displays troubles metabolizing alcohol because of a genetic variant that impairs production of an enzyme that helps metabolize alcohol in the liver. As a consequence, acetaldehyde, a toxic byproduct of alcohol, is not broken down to harmless acetic acid, but instead builds up in the blood and liver, causing headaches, dizziness, palpitations, and also sometimes nausea. Given this genetic variant, we are now considering additional indications for this product, specifically targeting liver diseases.

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Beside this glycol and methanol antidote, we are currently working on various drug development projects which would be eligible to 505 (b)(2) filling. Leveraging the experience accumulated when developing this new dosage form for alcohol poisoning, we want to bring this expertise to the treatment of other addictions that are particularly frequent in many Asian countries.

As UniPharma is becoming a more integrated healthcare company developing its own diagnostic products and drugs, how are you adapting the company's structure to sustain this impressive growth?

TL: In December 2016, we just received financial approval from Taiwan Stock Exchange's authorities and now plan to IPO in 2017. As a result, we need to remain profitable over the first half of 2017, as stipulated in the conditions of our public offering. In this regard, we have already been able to improve the profitability of the company by more than 100 percent in 2016, while our revenues increased 15 percent in the meantime.

This upcoming IPO indisputably stands as a great achievement for the company, and – after years of hard work –we have been able to ultimately reach this fundamental objective that we had clearly pinpointed as a strategic milestone in the development of UniPharma.

In 2010, UniPharma acquired the global development and commercial rights of Onko-Sure®, a cancer-detection, in-vitro diagnostics (IVD) product, which marked the company's first step out of traditional distribution activities. How have you been progressing in the international development of this game-changing product?

FW: Our business model for Onko-Sure® is already particularly well established: our manufacturing and distribution partner Pharmigene, located in the same building as UniPharma, has already received its GMP certification (ISO13485) while UniPharma was granted GDP certification in December 2016. Overall, Onko-Sure® received all certifications we needed to become available in strategic markets, including CE marking.

In terms of international business development, we decided to first target neighboring markets in the Asia Pacific region, with key countries being South Korea, China, and Japan. In China for example, we expect to complete our pivotal trial (phase II/III) by the end of 2017, and many potential partners have already displayed a strong interest in becoming our exclusive distributor in this country. Furthermore, we recently signed a new distribution agreement for South-East Asian markets encompassing Singapore, Taiwan, and Indonesia, while we are about to receive market approvals in Thailand, Singapore, and Indonesia.

We are also extremely active in Turkey, a market that we plan to use as a gateway to Europe, as our local distribution partner also holds solid connections to strategic European markets, where we are still focused on analyzing the region's regulatory and commercial specificities. We also received strong interest from Latin American and American companies, while our overarching objective would be to bring our product to the US market, the country where Onko-Sure® was initially

developed. Nevertheless, entering the US would require to find a partner holding extremely strong local resources, a great reputation and a long-standing expertise in this challenging market, in order to fully exploit the commercial potential of Onko-Sure®. We are currently discussing with some US-based companies to see how we could move toward this objective, although we do not want to rush our entry in this key market and will continue to favor a step by step approach.

Finally, in countries like Thailand and Turkey, we are extremely proud to see a strong interest from both government and private insurance sectors in using our product: overall, the feedback we receive from many international markets and their most important stakeholders is extremely promising and should allow us to be active in both the private and public sectors.

How has Onko-sure®'s development contributed to strengthen UniPharma's expertise?

FW: Overall, this product has allowed us to tremendously strengthen our understanding and capabilities in many areas relating to product development and manufacturing. Onko-Sure® was for example the first product for which we handled the setting up of a manufacturing partnership. This experience can now be leveraged in go-to-market strategy of our methanol antidote and all drug development projects we hold in our R&D pipeline. Finally, in light with the upcoming IPO of the company, Onko-Sure®'s on-going internationalization truly demonstrates UniPharma's ability to successfully broaden its activities and develop new areas of expertise, in addition to our core experience in the distribution field.

> "Revenues coming from distribution activities now make up 50 percent of our total revenues, and this share keeps on decreasing in favor of the sales of internally-developed products and treatments."

As a mater of fact, revenues coming from distribution activities now make up 50 percent of our total revenues, and this share keeps on decreasing in favor of the sales of internally-developed products and treatments. Finally, prior to our upcoming IPO, we managed to raise substantial investments from institutional investors, which now put us in an extremely favorable position to develop new in-house projects. In this regard, we are now actively looking for new products and even companies that we could acquire to further enrich our portfolio on the international stage.

As Director of International Business, what are your strategic priorities to nurture the overseas development of the company in the mid term?

FW: Onko-Sure® has already reached a rather mature stage of development and will then stand as the main driver of our international strategy. As a result, our objective is to move forward in the

registration and launch of this product in all strategic international markets. Nevertheless, we do not want to lose sight of the competitive landscape around this product because of our international ambitions, and we are focused on continuously improving our product to ensure it remains at the forefront of its product category. As a result, we are currently developing a new version of Onko-Sure®, which would make this product easier to use by healthcare professionals around the world.

Overall, UniPharma has managed to reach a level of development that now allows us to consider more ambitious growth steps for the company, be it related to inorganic growth or international partnerships. Thanks to our financial resources and our growing reputation overseas, without forgetting the quality of both our product portfolio and our R&D pipeline, we can now target bigger, more rewarding development opportunities, while UniPharma now holds the financial means and the expertise to become a true global player.

What would you like our international readers to think when they hear the name UniPharma?

TL: UniPharma is a Taiwan-based company with international ambitions holding a great experience of the pharmaceutical and medical industries. We really want to bring the best products to patients and target unmet medical needs, where our industry expertise and commitment to innovation can truly make a difference. Finally, as a public company, we hold a responsibility to our shareholders and employees to build a sound and fast-growing company which can compete on strategic international markets in all continents.

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