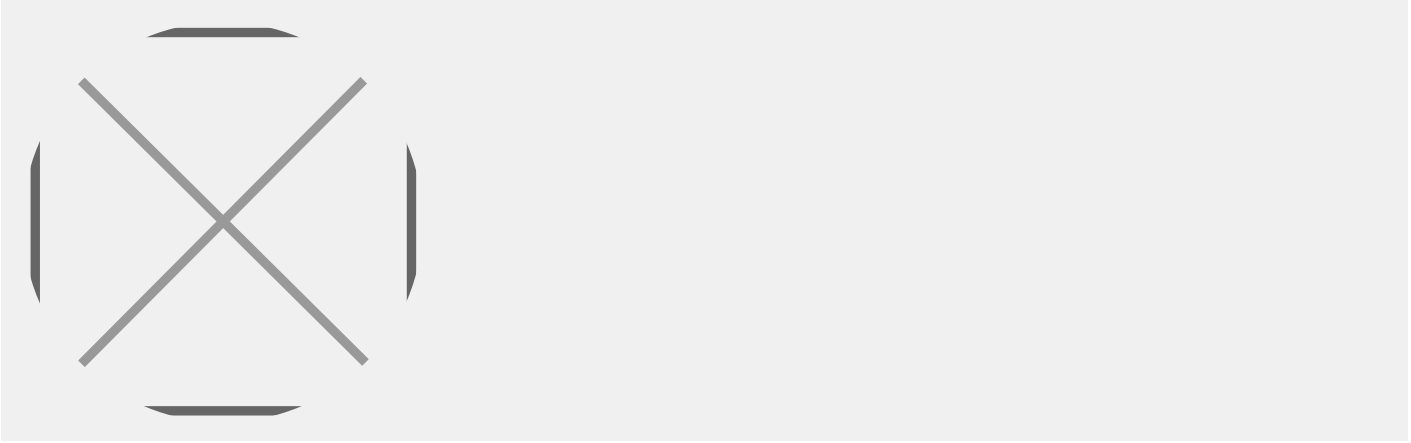
Interview part one: Chang Yi Wang, Chairperson & CEO, UBI Asia, and Chairperson & CSO, UBI



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In the first of this two-part interview, the chairperson of UBI and UBI Asia explains the work that her company has done to improve the landscape for Taiwanese pharma and biotech companies over the last fifteen years, and goes in-depth into the company's innovative pipeline, including UBI's possible HIV cure. To read the second part of this interview, click here.

UBI first invested in Taiwan in 1998. In 2004, you told investors, "Taiwan is *the* place to establish biopharma firms with international links." 15 years after establishing this subsidiary, and nearly ten years after you made those remarks, has the market continued to offer value to UBI?

It has—and the environment has improved greatly over time.

For instance, on September 9 2008, the chairman of the Taiwan Stock Exchange visited New York, and asked me to bring UBI to Taiwan for a public offering. From our perspective, the capital market in Taiwan had not been friendly to the biotech industry for the preceding 30 years. There was no chance for any company in our field to take off unless certain rules were changed. We made recommendations to the chairman that the exchange needed to eliminate the requirements of profits as a prerequisite for an initial public offering in order to truly nurture a group of highly innovative companies in this field. Also, it needed to establish an independent committee to assess the quality of the enterprises meeting global biotech and pharma industrial standards, to

allow the few companies that were truly worthy of capital market support to have no profit for a long period while investing in the development process. Investors would also need to be educated about the fact that it takes a great deal of funding to invest in innovative drugs, and the biotech business is quite different from the ICT firms Taiwan was accustomed to supporting. ICT companies operate on much shorter-term cycles, and are facility oriented. Innovative biotech is significantly longer term, and involves an inventive endeavor.

Furthermore, we advised on setting up a screening process to differentiate between truly innovative companies and distributors or manufacturers, to allow only strictly innovative biotechs to receive IPO certification. We expressed to the chairman the necessity to protect the quality of the companies that go public. Once a few low-quality players claiming this privilege are allowed onto a marketplace, that marketplace is doomed.

With the new reforms initiated and implemented by the chairman, the Taiwan biotech market has enjoyed a boom over the past few years. Though UBI, UBI Asia or any of its subsidiaries have yet to undertake an IPO, some of our peers have enjoyed tremendous capital gains. The market is understandably a little naïve, but investors are learning quickly, and the market cap growth in this sector has been remarkable to watch.

The gradual change towards innovation proved revolutionary for this country—just as revolutionary as the change I spoke of in the stock market. Since 1998, we have invested tens of millions of dollars into Taiwanese biopharma R&D activities, because we believe in the Taiwanese people. I always had confidence in them: I saw that they had a deeply entrepreneurial spirit, and that the state put a heavy emphasis on education. Pharma and biopharma innovation, I knew, would be able to take root here eventually.

At UBI Asia, we helped change the ecosystem. From the outset, we insisted on putting R&D as our first priority, and insisted on developing truly heavyweight products in this country. When we first arrived in Taiwan, the environment was quite immature. For instance, the country had no viable platform for the testing of antibody drugs while countries such as the UK and the US were already relatively advanced in this area. Despite the fact that Taiwan was investing in biotech, there seemed to be no cohesive planning. Taiwan had money and knew how to sell, and how to make generics, but they did not have experience in transforming researchers’ great ideas into commercial drugs. I have not seen any true biopharma products come out of Taiwan as yet, despite the establishment of an institution to bridge academia and industry. I believe this is because the emphasis in the past focused on technology development rather than product. Technology is important, but the ecosystem needs a product focus to elevate technology to the

next stage. A platform can deliver a thousand results—but which results? A market cannot build a technology platform without a product. Without a product, you cannot tie the pieces of the puzzle together! UBI's flagship HIV receptor antibody, which was tested rigorously in the US for efficacy in post exposure prophylaxis by offering sterilizing immunity or with precipitous viral load reduction in a treatment mode, was able to act as that catalyst. By utilizing this product, we have built a very solid antibody drug development platform and team. Now, with the platform and team in place, we can create a second innovative antibody, a third innovative antibody, etc. We can also link with government institutions to selectively license in their lead products and work on commercialization. We worked closely with agencies like the Center for Drug Evaluation (CDE) to obtain Phase I approval for drugs that were first-in-man. CDE had little experience in such matters: in the past, Taiwan was a hub only for Phase IV trials, or bioequivalence studies for generics. Nobody had looked to Taiwan for first-in-man research before us. Today, we can bring a pipeline of antibody drugs through Taiwan—some are already in Phase II, and others will soon get there.

The next stage will be to scale up. We are preparing for Phase III, and commercialization. The government continues to lag behind our progress, but we can help them to reach the same level.

Can you expound a bit further on the contents of your pipeline?

The flagship HIV product I mentioned is an entry inhibitor monoclonal antibody, UB-421. In Phase I of clinical testing, we noticed a significant viral load reduction, and moved to Phase II. We are moving toward a functional cure for HIV, not just treatment. Our drug has the unique property of preventing self-re-entry and cell-to-cell transmission of the virus, and is able to activate the viral reservoir. We believe that, if UB-421 is used in combination with HAART treatment, we may have a real breakthrough for an HIV cure.

For this product, we are working with the US Division of AIDS at NIAID, National Institutes of Health (NIH), the US Food and Drug Administration (FDA) to review the data, and multinational companies on global collaboration. This drug is not a local Taiwan project, or even a Greater China project. From day one, our company has been a global company. For instance, we have always stressed bilingual communication: as we know, no English, no science! We also are able to work around the clock, because as Taipei is going to sleep, New York is waking up, and vice versa. As we say at UBI, "around the clock, around the globe."

Our research, of course, also reflects the higher rigor of US standards. International quality is built into everything we do from the beginning. Our competition is biopharma companies like Amgen and Genentech.

Another of our flagship projects is an epitope based designer vaccine. This is a technology arena I have been working on for two decades. From the outset, I decided that I did not want to deal with classical vaccines—others could build those products better than us. Instead, we chose to work on epitope based peptide vaccines, and to work on areas like Alzheimer's and other diseases or infections where there are great needs beyond what the conventional biological vaccine approaches can deliver. An Alzheimer vaccine targeting Amyloid-beta is the most unique first peptide vaccine one can make.

Coupled with the platform we've built, I think this is another area where we might offer a breakthrough to the market. While we do have competitors in this field, including big Pharma like Novartis, Merck, Pfizer, and others I know we are the best.

For this vaccine, I brought the platform to Taiwan, and have worked with local agencies to allay their concerns about a first-in-man Phase I study. In Phase I, and again in Phase II, the drug proved to be safe, and the open trial data we've accumulated is excellent. We were able to generate site-specific oligo anti-A-beta antibodies in all patients—which is unusual for vaccines. We're talking about a 100 percent response rate! So far, we have seen an improvement in three out of three functional scores for patients with mild Alzheimer's disease (AD).

When we brought this very challenging product to Taiwan, we were testing not just the capabilities of the CDE but also the capabilities of the investigators in the hospitals, the contract research organizations, and our local clinical science team. As we have moved along the process both in HIV and Alzheimer's, we have not been disappointed. The data we have generated in Taiwan has impressed our collaborators in the West. We recently had a conference call with the FDA regarding our Phase II planning for the AD product, and they came away quite impressed.

It is not easy to conduct a Phase II study for an Alzheimer's vaccine that requires a PET enabled image biomarker for diagnosis of early stage of Alzheimer's Disease, but Taiwan is now the only country outside US that can do it. This says a lot about the quality of Taiwan's clinical capability. No one should underestimate Taiwan in clinical development. We only need a good product to bring that potential to fruition!

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