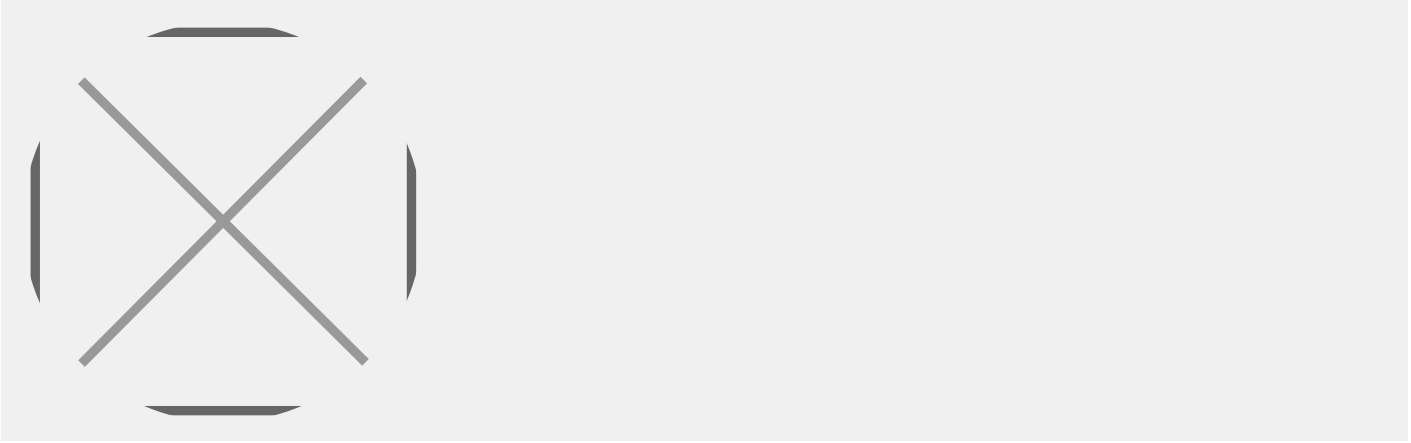
Interview: C.Y. Huang President, Phytohealth



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Phytohealth is a trailbalzer in the Taiwanese biotech industry: the first publically-listed biopharma company in the country, and the first company to receive NDA approval for a Botanical New Drug. What was the vision behind this business?

Phytohealth was founded in 1998. Its original purpose was to develop an extract from the astragulas herb, whichhas been a staple of Traditional Chinese Medicine (TCM) for thousands of years.

Our technology was licensed from a U.S.-based company, which had already spent over a decade working on the project. We are not speaking of a crude extract: the extract had been fractionated into polysaccharides, and the polysaccharides had been further purified to a specific molecular weight. In other words, it was almost as pure as a pharmaceutical—which is quite unusual for a natural product. Because of its purity, we were able to formulate it into an injection: PG2 Injectable. Our NDA approval by the TFDA, one of the first approvals of its kind in any country, was a breakthrough for botanical drugs.

When this company undertook an IPO in 2002, new sources reported that PG2 Injectable would be available on the market by 2004. You launched the product in 2012. How do you account for this delay?

At the time, the regulations in place on the market were not ready for us. The guidelines for approval, and the mentality of the reviewers, were very much geared towards pharmaceutical

products. If reviewers did not reject a drug like PG2, they would be breaching standard protocols.

It took a lot of time and effort for us to convince regulators that our drug was safe. They had little experience evaluating a mixture from an herb—and injections in particular must clear very high

How successful is PG2 Injectable so far, and what is your strategy for further penetrating the market?

PG2 is lucky to fall under the umbrella of our parent organization, Maywufa. The Maywufa Group can leverage not only its development arm—Phytohealth—but also its strong distribution arm in bringing the product to the market. Phytohelath develops and manufactures the product, and then passes it onto the Maywufa sales team for promotion. Bringing all elements together within the same group gives us great flexibility.

In Taiwan, most physicians prescribe only those drugs that are listed in the formularies. New drugs that reach the market for the first time are not listed—so our first effort is to convince hospitals to list our drugs in their formularies. We have been quite successful thus far: more than 13 hospitals have listed PG2. Every month, the number of hospitals increases. This work takes time, but we are doing quite well. The state, moreover, has lately put a lot of effort into supporting this industry. The Executive Yuan and Legislative Yuan released a joint communiqué to that declared that any new drug developed domestically should be listed in the national formularies.

We will secure the market in Taiwan first, and then we will look beyond our borders. There are currently talks underway between China and Taiwan about the possibility of fast-track approval for locally developed medicines. We are confident that once both sides of the Strait can agree, the China market will be wide open for Taiwanese drug companies.

Do you believe that botanical drugs are an idea that can find traction beyond Asia?

Yes. Very much so.

Certainly, modern botanical drugs will first find their niche in Asia: in China and Taiwan, and in Malaysia, Singapore, Indonesia, and Korea. This, by itself, is a big enough market—but we don’t have to stop there. As long as China remains strong from an economic and political standpoint, the international community will increasingly accept Chinese ideas. I believe that in time, the West will come to accept botanical drugs in the same way that they accept pharmaceuticals.

What else is in your pipeline?

We believe that we can develop PG2 into other indications. For instance, we have applied for clinical trial approval in the U.S. to test PG2 for ITP diseases. We have already received orphan drug designation, which will include fast-track registration, waving of the registration fee, and etc.

What is your partnership strategy for reaching a market like the U.S.?

Once we complete our Phase IIb trial for PG2 and other pipeline products—demonstrating proof of concept, safety, and efficacy—we will be able to negotiate with potential partners on good terms. But the trials have to be completed first.

Companies will want to collaborate with Phytohealth because we are a leader in the botanical drug area—and when a company goes into a partnership, it should select a leader!

Where will Phytohealth be in five years?

Our mission statement says that we want to be an Asian leader that has also found a global niche. In five years, we hope to achieve Asian leadership in botanical drugs—and, taking advantage of our expertise, we will leverage international interest in botanicals.

In the coming years, more and more botanical products will be approved by the U.S. FDA. These approvals will lead to increased interest in the botanical area from pharmaceutical companies. When that happens, we will be able to fully realize our advantages in this niche. Perhaps we will enter into licensing partnerships with major international pharmaceutical companies.

What is your final message to our readers?

This is just the beginning for new drug development in Taiwan. For many years, we have focused on electronics and ICT technology–but now, the state is looking at more innovative and long-term industries. More and more resources will be syphoned into biotech.

We are witnessing our first drug approvals—an indication that our worst difficulties are behind us. There is great potential for the future. This truly is just the beginning.

As for Phytohealth: as I mentioned before, the next five years looks very promising for our company.

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