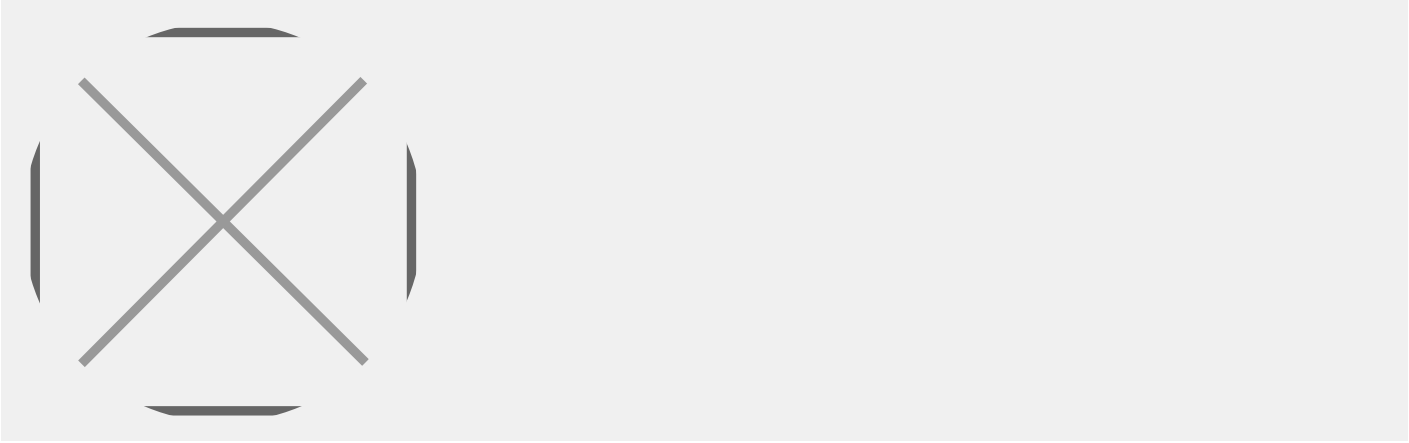
Interview: Calvin Chen, President, TWi Pharmaceuticals, Taiwan



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Dr. Chen, you joined US-based Anchen Pharmaceuticals in 2009 to help the company form a spin-off in Taiwan. Why did a US-based company look to establish itself in Taiwan, and then export back to the US?

In my view, the US is not a very attractive environment for a company of our type. Look at Watson Pharmaceuticals. Watson was a US company, but, through the acquisition of Actavis, was able to base its international headquarters in Switzerland. Companies are running from the US! In 2010, the Obama administration greatly increased the federal corporate tax rate, to about 35 percent. When compounded with state tax, Anchen's overall effective tax rate in Irvine, California was around 40 percent. This makes it very difficult to compete with major US-market competitors in generic and specialty pharma—some of which are in Europe, but the majority of which are in India.

Meanwhile, Taiwan has decreased its corporate income tax to 17 percent. Companies like TWi are also eligible for certain tax incentives, so we believe in the future our effective tax rate will be even lower.

Of course, some biotech companies do not yet make profits, so basing themselves in the US is not an issue for them from a sales standpoint. But Anchen had been fairly profitable for a number of years so we understood what tax could do to you. Our taxes had amounted to around 100 million USD in California, whereas in Taiwan, that number is closer to 30 million USD. With the extra 70

million, we can reinvest in product development, generate more products, and hence generate more income and bring greater benefit to our shareholders.

Would you have considered China instead?

Firstly, China has a higher tax rate. But perhaps more importantly, China's infrastructure is still lacking. Our business is in high-barrier generics. We use a lot of controlled polymer excipients to manage our drug release rate. Some of these excipients are not available in China, because of the difficult regulatory environment. Excipients in China are treated almost like active ingredients—logistics-wise, the CFDA doesn't make things easy.

We also have to consider the quality of the manufacturing operation. Indian companies have recently come under fire with the US FDA because of quality issues—in China, this could prove an even bigger challenge. There's only so much that a company can manage from the top. The manufacturing staff on the ground themselves have to have the right mentality. A sense of quality is still not common enough in China. It is very common, however, in Taiwan, because of our involvement in the IT industry over the last 20 years. In Taiwan, risk is lower in this respect and if we look at labor cost, the numbers are quite comparable on both sides of the strait.

It has been mentioned that 'difficult' generics are set to become 'simple' generics in the next few years. Do you agree? Is your high-barrier strategy sustainable?

Actually, I disagree. Our belief is that difficult generics will remain difficult for the foreseeable future. Firstly, nothing can change the complexity of the process. The margin of error is very small: if you let any contaminants into your production batch, you get a warning letter from the FDA. Too many letters and they will shut you down. Certain Indian companies will muscle their way into a market by offering half the price of the nearest competitor: but working at those prices leads to the compromises in quality I mentioned earlier. All your attention is on driving down cost. TWi tries to avoid price-war tactics.

Even if you can get the process right, the biggest barriers are perhaps the regulatory hurdles imposed by the FDA. For instance, products like sustained-release injectables require a fairly sizeable clinical trial to prove bioequivalence. Regulatory requirements are only increasing, and that means that the required investment and associated risk is also on the rise. The FDA is under political pressure to conduct especially stringent inspections of foreign manufacturers, which is only natural since they are a government agency charged with protecting the health of their own citizens.

Of course, if a particular niche in the industry can offer good returns, people will want a piece of the pie. We will always have to remain vigilant of new competitors. But if we look at the US marketplace for complex generics, there is a very dynamic equilibrium. Many generic drugs available today went off patent in the 90s, and although we would usually find seven or eight companies with the *capability* to compete on a given product, there are typically only three to four competing at a time.

A number of Taiwanese generics manufacturers are gearing up to go west. What is your key comment to your peers?

My key comment is that they should be focused. At TWi, we have 180 employees, and we spend approximately 25 million USD every year on research and development. Even with this level of resources, we know we will just barely be able to compete. We don't believe that some of our peers, who have invested less than TWi and yet seem to be trying to take on the world, are being realistic. Sometimes I wonder, "Do they know something I don't?"

One US-focused peer of yours said he knows that he will need more capital, and more scale, in the years to come. He believes that eventually, the only way forward for Taiwan's small and medium-sized generics companies will be to consolidate.

We will have to work together that's for sure. However, I believe that for cultural reasons, consolidation will not be very feasible. We have tried, with some success, to work as a consortium. Actually, we see the same thing happening in the API segment with ScinoPharm, which is contracting out to certain local partners. We have done the same for our finished products: for instance, we are partnered with Teh Seng in Tainan for one of our pipeline products, Lidoderm. Teh Seng is one of the top five companies in the world for transdermal patch production. We were fortunate to identify them as a partner after we completed our formulation work on the drug.

Taiwan's largest generics producer, CCPC, will manufacture another of our products. CCPC now has a dedicated facility to manufacture products that will be exported to the US. We were able to convince them to take this route: we told them that if you apply the quality standards of the US market to products you aim to sell in Taiwan, your costs would skyrocket. On the other hand, applying Taiwan standards to US-facing products is not good enough. To be clear, this is not because Taiwan does not care about quality—the rules are simply different because the scales are different.

How far along are you in the US now?

We currently have one ANDA product being approved by US FDA and another one with tentative approval. We are expecting three or three or four product launches in 2014. By the end of 2014, we will be able to say we are established in the market.

Currently, we have partnered with Teva and Parr for our product distribution in US. But TWi is going for an IPO this year in Taiwan, and one of the major reasons we are looking to raise this capital is to acquire a sales and marketing operation in the US. We want to build our own affiliate there.

The public market for biotech is quite hot right now. As someone with an extensive background in finance, what is your opinion of the environment?

You are right: the market is quite hot right now, and my background as a venture capitalist makes me look at the situation with a bit of concern. Certain Taiwanese drug development companies have out-licensed their compounds to US companies, and now their market cap is equal or greater than that of their US partners.

That seems very strange to me. In my experience, unless a US biotech can sell its own product they cannot become very profitable —unless they have the capabilities of a Celgene or an Amgen. Out-licensing your compounds, and taking part in a profit-sharing agreement, limits your capability to generate revenue, even if those products reach the market. Sometimes, your bottom line will still lose money, because in many cases, unless you have a home run, drug revenues are often not even enough to cover the cost of promotion.

The reason US investors recognize the value of smaller biotechs is because the typical expectation for those companies is that a larger player will acquire them. For the investor, it’s almost like buying an option. For instance, I personally invested in Optimer Pharmaceuticals, which ultimately got acquired by Cubist. At one time or another, other names, like Genzyme, were in the running to acquire them. This is the reason Optimer deserved to sustain its high valuation. But I wonder about the biotechs in Taiwan. What is the ultimate exit for their investors? We haven’t seen any such acquisitions in this country yet. If they are basing their stock acquisition on royalties, investors may really be overvaluing some of the drug developers on the GreTai exchange.

What does the future look like for the industry in Taiwan but also for TWi?

The interesting thing about Taiwan is that our pharma industry is very diverse. Some of our companies are definitely going to make it, although perhaps not the majority. I am looking forward to seeing Taiwanese pharma players reach the global stage. I don’t think people are taking us very seriously right now. Some may link us to China, but as you can see, I barely mentioned China in our

conversation. I believe that even for Taiwanese companies, China is very difficult, despite what some may say about our similarities in language and culture. The reality is that our strange political relationship complicates things.

As for TWi, the ‘i’ in our name implies our international ambitions. Unlike some of our peers, we have focused almost entirely on the US market. Only after we have established ourselves there will we start to expand outwards. If you have limited resources, I believe you should play in the market that will give you the best return. Our conclusion is that the US is that market for us.

Lastly, we do not want to be seen as a new drug development company that has a great story but no concrete idea of when they can turn a profit. That is not our business.

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