Interview with Jo Shen, Co founder, President & Chief Executive Officer, Board Number , ScinoPharm

30.07.2012

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ScinoPharm

2010 is ScinoPharmâ??s thirteenth year of operations. Thirteen does not seem to be an unlucky number for you as your company is doing particularly well at the moment. Perhaps you could start by telling our readers a little bit about the recent history of ScinoPharm and the good times that you have experienced over the past few years?

I can quickly avoid the number thirteen by telling you that the founders spent three years in preparation before starting the company! What we have experienced over the last couple of years and will continue to experience for the next five to eight years at least is that our investment and all our previous hard work is now starting to bear fruit. ScinoPharmâ??s major focus is to develop Active Pharmaceutical Ingredients (APIs) ready for generic formulation to use when originator patents expire. This description is fairly simple but the process takes a long time. In order to try and meet customerâ??s demands by providing APIs in sufficient time that they can be early to file and early to launch, we have to start development of our products five to seven years before we introduce it to the market. What ScinoPharm is currently experiencing is the reward for the work that was started five years ago.

This success has come because of the companyâ??s correct product selection, because ScinoPharm has done well in building up its customer base over the past ten years, because our products have been successful in meeting regulatory requirements and because our customers are doing very well in their chosen markets.

Five years ago, I knew exactly which products would be produced on a commercial basis this year, and I knew what kind of cost targets we would have to meet in order to remain competitive. I knew exactly what the IP situation and regulatory requirements were going to be. Today, delivering the bottom line is a matter of flawless execution, and as a team that has been built up since 1997, I am very confident that we have very strong capabilities to deliver what we promised.

The most important aspect of our work today is to plan for what is going to happen five to seven years from now. That is where our capabilities in selecting and developing the right products is key, allowing us to become primary supplier for our major customers and continuing to make sure they are satisfied with our product quality and customer service.

I understand that when you started ScinoPharm, for the first few years it was very difficult to convince people that your business model was going to be successful?

Before ScinoPharm, although several API companies existed in Taiwan in the past their marketing strategy was to produce products at the lowest cost and try to compete in existing mature markets. In order to do this these companies had to cut prices and success in this model depends on whether a customer is willing to switch source.

ScinoPharmâ??s business model is that before the train comes into the station we are ready to jump. Initially this business model was incredibly foreign to local investors. The first difficult concept for them was the role of GMP. They knew that GMP was important, but they did not fully understand that if an API manufacturing plant does not pass a GMP inspection from the US, then its APIs cannot be used for any customer who wants to sell their formulations in the US. This has to be the case for every country in which our clients want to market their products, which means that simply satisfying Taiwanâ??s GMP standards is not enough: the same wording does not mean the same interpretation during an inspection.

When ScinoPharmâ??s founders came to Taiwan with their investment plan, which involved building a GMP compliant facility that met with the most stringent requirements in the world, those of the US FDA, investors didnâ??t understand why. However, once they understood the necessity of FDA approval for a business with such international aspirations, they soon came on board. After pioneering this approach, other API companies in Taiwan have had much less difficulty in finding investors to support such a business plan.

The second issue that confused investors was the power of Intellectual Property (IP) rights in the API business. It is not only the substance or indication of a drug that is protected under IP law, but also the manufacturing process. Sometimes with processes the patent expires at the same time as the substance, but originators file numerous process patents right before their substance patent expires. This means that producers trying to get into that market have to bypass those patents, whilst still creating a product identical to the originatorâ??s, and doing this in a cost-effective way. Investors didnâ??t realise how powerful a skill it was to have that capability, and to be able to enter a market wherever you have taken care of the patent issue, and conversely how a particular patent situation can eliminate your chance of competing. There is absolutely no way that a serious API company can use an originatorâ??s processes and just wait to be caught. Doing this puts the business of the customers in jeopardy: they run the risk of not being able to launch important new products as a result. API companies cannot survive such situations, as they can no longer be trusted by their customers. In this industry, API suppliers and their downstream customers are really partners: it is not just a supplier-customer relationship.

Although investors eventually understood these two very important criteria, they still didnâ??t believe in ScinoPharmâ??s business model until the company started bringing in sales, and until the company broke even. We have proved that the business model is correct. Itâ??s a long process but until investors see a profitable bottom line they have the right to be sceptical.

I have to admit before I came to Taiwan I never expected to find one of Tevaâ??s biggest API suppliers here. Traditionally the worldâ??s strongest API markets are China and India. I would have thought it would be natural that such a large generics company would look to those markets to source their APIs. Why have they chosen ScinoPharm?

ScinoPharm has something that others cannot provide. When we started our company in 1997, the API industry was already very crowded. For a brand new company to step into this very crowded market the only way to attract customers is to do what other companies cannot.

When we prepared the ScinoPharm business plan in 1995, we were already looking at new products in the pipelines of the big pharma companies and new drug development companies. There were

very strong indications that there were going to be a lot of anti-cancer drugs and high potency small molecule drugs coming out in the years to come. We looked around and realised that at that time there werenâ??t any companies that had named themselves as API producer of choice for anti-cancer products. The founders of ScinoPharm came from Syntex. Syntexâ??s story is very interesting: it never lost a dime from the day it started up, and was the company that invented oral contraceptives, which are based on high potency hormones. Syntex built up its business based on their ability to develop and manufacture high potency products. The founders took what we were good at, applied what the market needed, and designed our facility and this company in order that ScinoPharm might be the expert in high-potency cytotoxic compounds, starting with anti-cancer drugs.

Most anti-cancer drugs are injectable. Injectable compounds usually require that the last few processing steps are completely free of microbial contamination, which requires very pure water. Right from the beginning ScinoPharm spent money and built its plant with a high purity water system. When the company launched, we told the world that ScinoPharm was an oncology company. We started with one or two products: today we have thirty products in the pipeline. Today, ScinoPharm looks at all the available information from the FDA about the inspections of standalone API plants being carried out across the world. Out of these inspections there are 294 plants that the FDA have inspected for one or two products. The FDA has inspected our entire plant three times. Of those 294 plants, around 20 can produce the same kind of anti-cancer drugs that ScinoPharm can. However, with the FDA companies also have to register their individual drugs. How many different DMFs does each company have? Some have ten or fifteen compounds; some companies have less than five products. ScinoPharm is way above this, and every year we have launched more and more products.

Today ScinoPharm has launched only three anti-cancer drugs. However, the number products yet to be launched because of the expiry of originator patents is close to thirty. Generic companies developing injectable anti-cancer formulations now come to ScinoPharm and find out what we are working on in the research lab. The major companies will suggest new potential drugs to develop, and ones to leave alone: the company receives a lot of its market intelligence directly from the customer.

Whenever we finish research and development and go into production to make the first GMP batches, the products are shipped to the customer as soon as they are ready, in order that they might be used for drug development and formulation work. It is seldom that we develop a product and there is no customer. The only way that we can enjoy this enviable situation is that there are very few competitors who can do as many oncological APIs as ScinoPharm. I am not saying there are no competitors: there are many: when our business model became a model for success, many people tried to follow us.

Are you still experiencing ScinoPharm being first to market with these products, or are companies getting faster than you?

We are the supplier of choice for customers that have to be the first to market. Thatâ??s how we operate. Another beautiful thing about this business model is that there are not too many companies that compete to be first to market. If your customers are in a very crowded space, they have to cut prices, which means that they come back and cut your price. In ScinoPharmâ??s field there are fewer API competitors. In the customerâ??s field there are also relatively few. Solid dosage form originator drugs often have 30-40 generic versions that all launch on the day the patent expires, but oncological injectable formulations will have only five or six generic companies looking to launch their versions. If all of these companies were our customer, that would be great, but we always aim to have at least the top two companies as our customers. When we have that ensured, ScinoPharm

is assured that products created from its APIs will be the first to launch.

A lot of Taiwanese companies view the world as their market rather than just the country because of its relatively small size. What influence do you think Taiwan has had on the way ScinoPharm positions itself globally? What does ScinoPharm owe to Taiwan and what does Taiwan owe to ScinoPharm?

For most local companies, their first market view is South East Asia or China, and yet there is a smaller group today trying to aspire above this and penetrate regulated markets. In those cases there is still a lot for these companies to do to fully understand the patent situation and GMP requirements. Both of those things require investment. Right from the beginning ScinoPharmâ??s business model was that the world was our market: there is no reason why being registered in Taiwan means you can only look at Asian markets. In fact ScinoPharm sells very little in Asia compared to the rest of the world. In Taiwan we only have one customer and in Japan we are just opening the door because generics were not interchangeable until 2005. We currently have no sales in China and South-East Asia. Our major market has always been the top tier, the most regulated markets: The US and Western Europe.

Taiwan has provided an environment where if you have the right business model and a good management team, the country will provide resources in terms of financial investment, land, tax incentives and people. Taiwan has a very good education system. Students are very hard working. They pay attention to details and also to quality. The diligence and the work ethic in Taiwan is something I am very impressed with. I was born and raised in Taiwan but I left for the US for over thirty years. I finished college and went to the States. After spending my working life in America, I can honestly say that coming back to Taiwan I have never seen such a hard working group of people. I have to chase people and tell them to go home! People have a strong sense of responsibility and commitment. I think that this is what Taiwan provides.

The government has clearly defined its strategy for the biotech and pharmaceutical industries. They created an investment fund that ScinoPharm took advantage of, as well as receiving investment from Taiwan Sugar, a state-owned company. The government also provided low interest long-term loans: ScinoPharmâ??s plant was built based on its ability to borrow. Then they provided the land. The land where the factory currently stands was rented rather than purchased. If I had to purchase this land even ten or fifteen years ago it would have cost U$ 30-40 million. They also allow pharmaceutical companies to operate tax-free for five years at any time of their choosing the tax-free incentives for the first five years. This system is very well designed.

The government provides research grants. No other countries could ever compete. Each and every single pharmaceutical company in Taiwan will tell you they have one or two research projects happening that are 50% government-funded. Investment in research and innovation will allow Taiwan the success it deserves in the long run.

What do we owe to Taiwan? Firstly, we stuck to the aims of our business plan and in doing so have helped other API companies on the island because of the cluster effect. ScinoPharm will continue to bring income to the island: the company pays its taxes here and we are helping the pharmaceutical industry by building national exports. In the last few years the Taiwanese pharmaceutical export business has grown, and the majority of this growth is coming from ScinoPharm. Exports are growing much faster in the API sector than in finished products. 99% of ScinoPharmâ??s production is exported. The comapny has already put Taiwan on the world map for oncology related API supply. I hope in the long run we will do more than that, and that ScinoPharm will become recognised as a peptide producer and as a producer for biopharmaceuticals.

We also hope our companyâ??s vision doesnâ??t limit itself to Taiwan. The world is our kitchen and we want to cook in it. The market could be anywhere. In that light, ScinoPharm has had a branch in China for over nine years now. The site is quite limited, so we recently bought another piece of property about 40 minutes away from our current site. It is the companyâ??s goal that once that plant is built we will move most of our people there. The new site is going to be as big as the one in Taiwan. The plan is to continue using the site to support our current business model by either producing intermediates or certain APIs for existing markets in the US, Europe and Japan. However another branch of our business we can consider for our Chinese plant is the Chinese market, where we have never been previously. That market may require different kinds of products, or require us to work with a formulator all the way, or maybe build our own formulation facilities. We will not limit ourselves only to think of ourselves as an API supplier.

In Taiwan ScinoPharm will always be an API supplier, but in those markets where we already have customers we will not compete with them. We will continue forever to be their partner. Our customers have never established their businesses in so we will have an opportunity to at least selectively try and enter that market.

The third objective is that the plant could be used for contract manufacturing. There are a lot of big multinational pharma companies looking for contract manufacturing capability in China but they have to find some people they trust in terms of safety, GMP, and also the protection of IP. Currently, a smaller part of our business in Taiwan is contract manufacturing for big pharma or NDD companies in either the commercialized mature product area or the new drug area. We already have a good reputation and interaction with those customers, who keep asking when we are building our plant in China.

Do you have a final message for our readers? What would you like them to know as a final thing about ScinoPharm?

Watch out, Taiwan is coming! The government will work with the universities and the industry and provide a very lucrative environment for innovation, for new drug development and for every part of the supply chain. For example, a lot of companies are looking at becoming a hub for clinical trials. Taiwan has already become a hub for certain APIs. Eventually Taiwan will develop many different specialties across the whole value chain. Because of the countryâ??s relationship with China, collaborations between Taiwanese and international companies for entering the Chinese market will give them a much lower risk approach and a better chance for success.

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