Zhou Mingdong – Founder, Chief Executive Officer & Chief Scientist, Zensun

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One of the earliest innovative biotech companies in China, Zensun has developed what its founder Dr. Zhou Mingdong calls a rare made-in-China first-in-class therapeutic candidate, Neucardin®, which has been shown to improve cardiac function, quality of life and exercise capability, and, to reduce all-cause mortality rates in certain patients suffering from heart failure. The National Medical Products Administration (NMPA) of China recently accepted Zensun's New Drug Application (NDA) for Neucardin®. Zensun is now expanding its new drug development to therapeutics for aging related diseases associated with deteriorating organs, including Alzheimer's disease and functional constipation.

We recently read an Opinion piece in the New York Times by Thomas Friedman entitled "China Needs Its Own Dream," which talked about the differences between the American Dream and the Chinese Dream. We're curious to know: what was your dream in founding Zensun, and do you think it differed from what it would have been had you not been abroad for so many years?

First I'd like to start with a brief introduction to Zensun, which is one of very few companies in China focused on innovative drug development. The company is a very good example of the fact that Chinese resources can be combined within the global innovative framework. The progress we

have made in developing our most advanced drug called Neuregulin, for the treatment of chronic heart failure. Chronic heart failure disease is a big problem globally, but for 20 to 30 years there have been no significant breakthroughs. Previously, there have been ACE inhibitors, beta-blockers, and ARB drugs developed in Western countries, but no further progress has been achieved, and the death rate remains very high. There are two groups of scientists involved in chronic heart failure research. One group studies the vessel system, and the other, much smaller, studies cardiac muscle cells. So far, all the drugs I mentioned are for the vessels.

The analogy I like to use when speaking of these treatments is the following: it's as if the pump is failing, but you're repairing the pipe! Unfortunately, scientists have only studied the pump – the heart – and have not made any significant progress. We want to tell people that history has stopped at this point, and open a new page. That's where Zensun comes in, and the dream was to bring international study results, and eventually a drug, to China. 12 years ago I was an investigator in Australia and I had an idea supported by very preliminary research data, and at that early stage the dream was to bring it to China. At the beginning of this century, there was a period in which everyone was very influenced by the IT bubble. This time lasted only two to three years, and any success was hard-won, but during this time when I brought the idea to China, it was easier to attract investors – it represented a new hope in an old land. The people in China were willing to put money in the field, even though the money is small relative to the US or European standard. Fortunately, in China a little money goes a long way.

Now, Zensun's drugs have become very promising; we're filing NDA in China, and we're almost finished Phase II clinical trials in the US as well. In fact, we were able to file NDA with our Phase II data, because it was so promising! We were very lucky that when we did Phase II, we also designed a survival study for the drug. Finally the survival study was very successful, and it shows that comparing to standard treatments, NRG-1 further reduces mortality by a staggering 60%. In China, Phase III is still ongoing, but we've already filed NDA which will hopefully reach a successful conclusion by the end of 2012 or the beginning of 2013.

This story reflects very well on the Chinese people, and shows that they are now capable to combine their advanced knowledge with the world. They have succeeded with furniture, buildings, highways, high speed rail and other infrastructure. Now we have shown this same capability even in a very sophisticated field like novel drug development.

Zensun has its hands in a lot of pots, from the science side of things and technology services, **to partnership possibilities and business development. What's at the top of your priority list, and how do you divide your time?**

I spend about 80% of my time in fundraising, beginning with Chinese fundraising, and now shifting internationally, and looking to co-development, licensing or co-marketing possibilities with Big Pharmas. Novel drug development is a global business, so it's very hard to be finished by one small company. The typical model is that usually a small company develops the early stage, then ships to a bigger company which does the downstream work and finalizes development. We obviously have the dream to finish everything by ourselves, but we recognize that this may not be realistic, and that's why we are open to the opportunities I mention above.

Usually, Big Pharma wants worldwide exclusivity. Previously, they were unconcerned with the China market, and might not care to include it in the deal. But now they're much more interested. And now that Zensun is also growing, we're not only interested in the China market, but Europe, US, and Japan, Australia, or Canada. That's why the negotiations are much more complicated now, because we're trying to keep some of the rights with us.

You've been a scientist in a smaller innovative biotech company, and now you're spending 80% of your time as a negotiator and fundraiser. How have you managed the transition?

It's difficult, but you don't really feel it. You may leave school at 28 or 30, after your PhD, but now I'm close to 60, and the whole life for everyone is the same. In the end, you don't do many things you learn from school, but things you learn from society! That's the story. To build things, you learn and feel for what you don't know. For what is unknown, you get interested, then you meet people, publish articles, debate internally and externally with friends and external experts, and gradually mature. Obviously there's a cost to all this, but fortunately, we haven't made any fatal mistakes. Also, the principles in business and the science are the same. In business, you need some innovation. If you have the ability for innovation, then in science you'll see things people missed, and it's the same in business, even if usually people don't think this way.

When will be see **the first Chinese blockbuster, and will it come from Zensun?**

So far, we are the only company I know of with potential to make the first! With our NDA in China by next year, and in the US by 2015, it's a real possibility.

If you're going to get NDA approval for Neuregulin, it will change the company fundamentally. Paint us a picture of Zensun in five years; where will you bring the company and how will you get there?

Most likely, Zensun will evolve to become medium-size on a worldwide standard for biopharmaceutical companies, such as Biogen Idec. There are so few companies that evolve to be in such a position. Why are we confident? I'm not overconfident, and I don't promise success, but that's our target. We'll start with one blockbuster and share our success, and share a certain part of the market with partners, and then the basic science and drug development projects will build up. Now, the recent targets for us are not scientific, but to build the business. At the end of 2013 or beginning of 2014, we want to be listed on NASDAQ or the NYSE. And the deals with Big Pharma should be finalized by the end of 2012 and beginning of 2013. We're on track in these regards because of the scientific data, but most importantly because of the survival data!
Of course, there is a difficulty in the ambition of wanting to be listed on the NASDAQ or NYSE. One is that Chinese stock prices have been depressed lately, which has given a bad image to the sector. Secondly, in China the innovative business is not very active. People were worried about whether China can really innovate, and why blockbuster drugs aren't developed in China. It's a cause for some people to worry. However, Zensun has overcome this in two ways. The first is by simply repeating the Chinese data outcomes in the US. And second is the fact that if Big Pharma isn't worried about it – and they aren't! – why should anyone else?

As a final message to Pharmaceutical Executive readers – whether they are interested in co-development, or as potential investors – what do they need to know about Zensun?

Zensun isn't a Chinese company – we're a global company. We have a global research team, and I as a founder and overseas returnee ensure all our research is done to Western standards. I'm not only referring to process. For me, the biggest issue is the science principle. We at Zensun respect science and we follow science and reason. That's why the data we generate in China can be trusted to the same high quality as anywhere else in the rest of the world.

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