Irwin Wang – CEO, Reistone Biopharma, China



I realized that if I wanted to establish a global biotech company in Shanghai, I should look to work with Chinese companies since they would be looking to work on global trials but would lack the necessary capabilities due to their lack of exposure to international markets

16.10.2019

Tags: China, Biotech, Reistone, Jiangsu Hengrui, Research, Clinical Trials

Dr Irwin Wang, CEO of Reistone Biopharma, shares her motivations behind the establishment of the company, their extremely productive collaboration with Jiangsu Hengrui (China's largest pharma company by market capitalization), and their exciting international clinical development strategy for their three assets.

Irwin, could you please share your motivation for establishing Reistone Biopharma?

I trained as a physician and subsequently continued my career in Canada running global programs for Bayer. In 2005, due to the increased importance of the China market to Bayer, I was sent back to Beijing, where I worked for Bayer for eight more years before joining GSK and then Takeda. I can be considered part of the earliest wave of overseas returnees. During my long career with Big Pharma companies, I became familiar with a myriad of different products as well as the corporate organization, and in 2017, I decided to join Qiming Ventures. That was very exciting for me because I saw a different side of the business. I had the chance to work with a few of their portfolio companies, including Zai Lab. However, as an investor, you only have an arm's length engagement with the portfolio companies. Biotech companies typically expect investors to provide money or advice, not to get too involved with their daily operations. I missed being involved with the actual drug discovery and development work, which was what finally inspired me to establish my own biotech company.

Reistone Biopharma was established in January 2018. Since I come from a global pharma development background, I wanted to establish a global biotech company. From my Big Pharma experience, people in China liked working on global studies but rarely had opportunities to do so since most Big Pharma companies did not have extensive R&D operations in China. When I was with Bayer, we established an Asia team and I oversaw many global and China trials, managing teams of up to 140 people, but in general, China teams often do not get the chance to truly take the lead on global programs. Even companies with R&D investments in China like AstraZeneca, Roche and Bayer soon withdrew their global teams due to the cost of bringing in global talent and the underdeveloped clinical infrastructure in the market.

Therefore, I realized that if I wanted to establish a global biotech company in Shanghai, I should look to work with Chinese companies since they would be looking to work on global trials but would lack the necessary capabilities due to their lack of exposure to international markets. Based on my expertise and experience, I thought I could build a biotech company to fill that gap.

What has been the key milestones for Reistone over the past few years?

The first must have been finding the right strategic partner to work with. Looking at partnering with Chinese pharma companies, the first that comes to mind must be Jiangsu Hengrui as the largest Chinese pharma company by market capitalization. They also have the largest innovative product portfolio and existing international operations. Both sides thought we would be a good match, and ultimately, they invested USD 100 million in us, which is a very significant amount. This enabled us to get started.

While many Chinese biotechs start from the pre-clinical stage by developing their internal assets, we decided to start by in-licensing three assets from Hengrui and building a clinical team. Clinical development is our area of expertise and we quickly built a team, adding key roles like CMO and regulatory affairs. In total, we now have nearly 70 people.

Our focus is on autoimmune diseases, which we see as an area with great potential because these are chronic diseases, and patients with autoimmune diseases also live longer compared to patients with cancer, for instance. In addition, immunology is now becoming a very hot research area within the industry, and many mechanisms of action have been identified. Compared to CNS, for instance, it is not as complex or untested an area to work in. The main challenge is how to develop drug candidates compatible with the steroids currently being used to treat IBD. Steroids work to control the symptoms but do not actually treat the disease itself.

We currently have three assets in six programs at the moment, four in Phase II and two in Phase I.

Could you share more on your clinical development strategy?

We are running Phase 2 programs across China, US, Poland and Ukraine for our flagship drug candidate SHR0302 for two types of inflammatory bowel disease (IBD), ulcerative colitis (UC) and Crohn's disease, as well as atopic dermatitis. SHR0302 is a novel and orally administered selective Janus kinase 1 (JAK1) inhibitor. This is quite a large global study for a small biotech. We are running the trial ourselves in China and we hired IQVIA to run our global trials.

Overall, we are running clinical trials in five countries – the above four and Australia – which is very exciting.

Due to the importance of managing compatibility with existing steroid treatments, we thought that clinical trial design would be very critical. A drug might be a good one but if the trials are not designed or run well, they could still fail. This is why clinical expertise is so important.

We decided to run trials not only in China and the US but also Poland and Ukraine because based on our extensive experience, both markets are very good for patient recruitment. They are not as advanced as Western European markets but they actually contribute the most patients to clinical trials across the whole of Europe. Patients in Poland and Ukraine are more willing to participate in trials to access new and innovative therapies, and physicians are also more willing to run trials to access new medicines. Since speed is key in Phase II studies, we thought it would be useful to run our trials there.

We have also built a very strong clinical team with people possessing extensive Big Pharma experience. We have also assembled a strong external network of KOLs as well as the services of leading CROs like IQVIA, which has a lot of experience in IBD, for instance. By the end of 2020, we hope to start our first Phase III trials, so we are very excited for that.

As Reistone grows, what additional capabilities do you plan to add?

We are now starting to build a translational team to help us work on future preclinical assets. We have established a team in Boston as one of the biotech hubs globally, and we are working with different universities and CROs as needed. We also look forward to gradually building our discovery team as we find the right people. At the moment, we do not think it is necessary to build our own

lab at the moment since we do not have the real need for it at the moment. But once we have the right discovery scientists and talents, we will see if it makes sense for us to establish our own lab.

Since we have established our HQ in Shanghai, we are also starting to assemble our global team. In general, people are not so used to working for a company HQed in Shanghai so there are some operational or cultural aspects for us to adjust and our employees to adapt to. What is positive is that since we are a China-HQ company, our employees have the opportunity to work for a global company running global trials. This is a very attractive opportunity for many people.

We are also looking to acquire new assets, ideally earlier-stage since we already have later-stage candidates now, and later-stage assets are also more expensive. We want to look for new modalities and platforms that could complement our existing portfolio. We would also prefer global rights and global assets but if we see interesting assets with China rights available, we would also consider them.

How have you found working with Jiangsu Hengrui as a strategic partner?

I think we are working very well with them. It was great to have a strategic partner rather than just investors. Investors can offer a lot of freedom to biotechs and help with identifying the best board of directors, IPO and financing, but strategic partners – like Hengrui – can offer a lot on the operational side. They can support your product portfolio, supplement drug discovery and development capabilities, and offer expertise across all aspects of the value chain. We received a lot of support from Hengrui and that helped us build up Reistone quickly.

Strategic partnership is a well-established concept outside of China but Chinese companies are only just beginning to understand this. Most of them would have only worked with API and other independent suppliers, for instance, so the idea of strategic investing in a separate and independent entity might still be foreign. However, Hengrui is a very progressive and adaptable company – which is why they have been so successful – because they are smart and learn quickly from what other global companies are doing. This is also why our partnership has been so successful.

Could you outline your plans for commercialization of your current assets?

We have begun to discuss this internally but will continue to evaluate our options. Internationally, Hengrui does not yet have strong networks so we will see who we should work with. In China, Hengrui has strong experience in areas like oncology, medical imaging and anesthesia but not in auto-immune yet, so again, we have several options to consider. We could either license the asset back to them, build our own salesforce or even work with other sales organizations.

With so many biotech companies being established in China, talent competition is fierce. How is Reistone dealing with this?

This is definitely a challenge. The positive aspect is that it makes it easier to recruit global talents – including overseas returnees – since they are no longer noticeably more expensive than local talent. Of course, the costs are still high and we have to deal with that.

Reistone is a very attractive biotech company to work for because, as mentioned, we are running global trials. This gives talented people many more opportunities to develop their skills and expertise. Even people working for Big Pharma companies in China might only have the chance to work on China trials since not so many global trials are being run from China. This is why our employees are happy to work here, since it benefits their own career development too. If they decide to leave Reistone in the future, they would be able to leverage their experience here. In addition, as soon as we strengthen our US presence, our teams in both the US and China would be able to move between both offices. At the same time, it is also challenging for our team because they can no longer rely on going to HQ for help, they *are* at HQ now and they have to solve problems themselves. Of course, we do rely on the help of external independent consultants to support our operations.

To be proactive, we have also hired an external HR consultant to help us develop a HR strategy early. This will help us learn how to motivate people, retain them, and overall foster a better working environment.

On a more personal note, having worked in the medical, research and investor sides of the industry, what would you say motivates you?

What is positive is that I have been a manager in various capacities for 15 years now. I was not coming immediately from a purely scientific background so management was not new to me. During my time with Big Pharma, I had worked not only in clinical development but also medical

affairs, marketing, medical science liaison and so on, often working very closely with the commercial teams, so I was familiar with the entire pharma organization as well.

But I knew it was important to be strategic about Reistone's success, not just in terms of its clinical development but also in its overall development as a biotech company. We are currently working on 'me better' drugs so the focus is on affordability but our next wave will focus on innovative drugs.

As a global biotech, we are very focused on taking Chinese-developed products into global markets. Chinese companies in all industries have gone global now, from mobile phones to household appliances to Internet companies, but there are still barely any Chinese-developed drugs available in global markets. We are still behind when it comes to pharmaceutical innovation but this also implies opportunity. Reistone would like to develop innovative drugs for global markets and become a pioneering global biotech HQed in China.

See more interviews