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## Betting On China For New Drug Development

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Healthcare investment firm OrbiMed manages over \$14 billion in public and private equity, nearly \$1.4 billion of which is focused on Asia. With 23 private equity investments in Asia, OrbiMed is spreading its interests across the healthcare spectrum, including drugs, medical devices, services and enabling technology.

Jonathan Wang, senior managing director at OrbiMed, joined the firm in 2007 to build its Asia business from scratch. The firm now manages two Asia private equity funds that combine for more than \$500 million. Wang is a prominent figure in China's healthcare and life sciences space, and he is cofounder and former chairman of BayHelix, a business organization for China healthcare and life sciences leaders.

Mr. Wang spoke with MedidataVoice from Shanghai about the outlook for healthcare and life sciences in China and emerging markets.

### **What are some of the biggest differences between the China and West pharmaceutical markets, especially in terms of innovation?**

Generally speaking, there is less innovation in China than the West, which means generics weigh more in China. Over 80% of the Chinese pharmaceutical market is generics. That percentage is multiple times higher than a developed country like the U.S.

Innovation in China is improving. More and more companies are developing me-better and bio-better drugs – improved versions of marketed



pharmaceuticals. There are also Chinese companies that develop drugs with in-licensed compounds from the West.

China's pharmaceutical market is much more driven by market needs than innovation. The disease areas that local companies focus on have a lot to do with the market needs and the local disease profiles, which are different from the West. For example, there are over 100 million hepatitis B patients in China. It's a huge problem, but not so in the U.S., where hepatitis C is a bigger problem. Hepatitis B, diabetes, and liver, lung and gastric cancers are all popular disease targets for Chinese companies.

### **What are the hurdles to innovation in China?**

One hurdle is the regulatory environment. It's difficult to get a drug

through the CFDA approval process in China. The IND (investigational new drug) approval, for testing a drug candidate in humans, would typically take weeks in the U.S., but months, often over a year, in China.

New drug approvals (NDA) in China have a long wait as well. These delays choke innovation. When a company looks at what's ahead for its compound and compares China versus India versus South Korea versus Australia, it would often go to another country because it doesn't want to deal with the inefficient and long approval process.

Drugs already launched in the West would typically experience five to seven years of delays before launching in China. Approximately 50% of the top-selling global drugs launched since 2008

are not yet accessible to Chinese patients. If that's the case for approved drugs, imagine how long it takes for new drugs to be approved in China.

Another hurdle is China's shortage of drug development talents. The talent pool has been an important limiting factor in China's growth as a pharma innovator. China has been hungry for talents who understand high quality drug development, have a global view and can talk the same language as their Western partners.

This talent pool, however, has been growing rapidly, especially over the past five to 10 years. There are many returnees from the West who have been trained at first-class global institutions.

They have started their own companies or joined local companies and have become leaders in drug development in China.

Also, the financing environment in China has been a limiting factor for innovation. In the U.S., people are used to investing large sums and waiting for a long time for a drug to be developed. In China, that concept is relatively new. Recently, however, as the drug development industry matures, investors in China are becoming more comfortable with the concept. Financing healthcare has become popular over the recent months.

### **What are some of the local China companies worth highlighting?**

There are many Chinese companies worth highlighting, but a few that come to mind are Chipscreen, led by Xianping Lu, Zai, led by Samantha Du, Beigene, led by John Oyler, and Hua, led by Li Chen.

### **What are the risks to investing in innovation in China?**

The risks are related to the hurdles we just discussed. First, the regulatory roadblock is a big risk. CFDA has been conservative, slow and extremely risk

averse, so the waiting list for drug approvals is very long. If a compound cannot reach its next regulatory milestone, the company's value will not increase and investors will be less likely to invest more money.

Another risk is a shortage of high-quality drug candidates in China. Due to the relative short history in innovation, China has not yet created a robust supply of good compounds and still depends on cross-border in-licensing for many of them.

Also, there is the risk that some local teams are not equipped with the know-how to conduct high-quality drug development. Sometimes an incompetent team can destroy a good compound if the design of the clinical trial is inappropriate.

### **Are there ways for companies to deal with the difficulty to gain IND approvals in China?**

Some companies go to places like Australia or Taiwan for Phase I clinical trials. Once a compound has been tested in humans elsewhere, it's easier to get CFDA's approval for clinical trials.

### **How do pharma companies in China rank the following in terms of drug development priorities: improving quality, lowering costs or increasing speed-to-market?**

They are all important, but what I have heard the most is that improving speed-to-market is essential in China. Costs in China are usually significantly lower than the West, so the most urgent problem is between speed and quality. I have heard more complaints about speed than quality because of the regulatory situation.

### **If you look forward, how do you see the China market evolving?**

Innovation will grow, because product differentiation is becoming increasingly

important in the market. As a result, the weight of generics will continue to go down.

In the next 5-10 years, China will create multiple first-in-class or best-in-class pharmaceutical products, which has been the Holy Grail for Chinese drug developers. I've seen so many teams working on so many interesting programs, and, given time, some of them will succeed.

Moreover, biologics, especially biosimilars and bio-betters, are probably going to boom in China. Many companies are establishing GMP manufacturing capacities and developing biosimilars targeting blockbusters like *Humira*, *Rituxan* and *Herceptin*. There are usually 5-15 competitors pushing their bio-similars through the regulatory approval process for each of these targets. Someday, some of these Chinese biologics will be sold in other regulatory markets as well.

I also see an increasing trend for Chinese companies to go abroad. Up to now, China has had an influx of technology and compounds but I believe the outbound trend is going to emerge and grow.

### **Any final thoughts on innovation in China?**

Innovation must be for market needs. People should think about the market needs for the drug before thinking about how to develop the drug. If someone asks for \$100 million to create a new drug, some of the first questions on my mind are how will the drug sell, how is it differentiated from competition, and is there a need for such a drug.

Innovation is only a means to an end. I invest to make money, not to innovate. People sometimes pay too much attention to the means but insufficient attention to the end. 🍷



An interview with **Jonathan Wang**

Dr. Jonathan Wang is a senior managing director at OrbiMed Asia, which he co-founded.

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