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China Life Sciences: Moving Towards Full Impact

By Julian Thurston

I recently spent some time in the "Golden Triangle," which on its Northern edge is delineated by the area between Nanjing and Shanghai. What is initially striking is the absolutely mammoth investment in infrastructure that has occurred in this region in recent years, and is continuing to occur. The Shanghai/Nanjing bullet train is due to open in 2011 and will reduce the journey time from over two hours to down to 50 minutes. It is in this region that most of the 250 million middle-class Chinese live and work. Most of the families using the more highly-priced Western drugs will be in this region. The overall infrastructure is striking — with the huge modern airport, several times the size of Terminal 5 Heathrow, with mile-upon-mile of elevated highway with not a single pot-hole, and with literally hundreds and hundreds of apartment blocks built in the past few years. Then there is the infrastructure for life sciences R&D based in and around the leading science parks. And it is not a question of these facilities standing empty as they do in relation to many equivalent projects in the Middle East. These facilities are full of scientists going about their business. How has this been achieved?

At the time of the Cultural Revolution and for many years afterwards, the bright, well-connected Chinese sought to study in universities abroad, particularly in the USA, and had an aptitude for subjects like mathematics and science. This lead to them being natural recruits in the research-based pharmaceutical business in the USA, both by the largest companies and by the biotechs. When the lights in Kendall Square were on at 11 p.m., it was often a Chinese scientist who was still working at the bench. The Chinese government has been anxious to attract the best of these scientists and their families back to China and has given them considerable financial incentive to do so. There are now more than 60,000 of these returnees or "sea turtles" working back in China, seeking to make true the slogan that you read all around the Golden Triangle region: "no more low-cost manufacture, now low-cost R&D." Chinese government provincial and municipal grant money has been available for some years for the best of these sea turtles and now upwards of US$1 billion a year is allocated to the best of these projects. The lead scientist in each grant-supported project is likely to have working with him at least four to five other post-docs, and these small groups of scientists usually work within the structure of a start-up company. You discover that there are several hundred such start-up life sciences companies in the Golden Triangle, each pursuing their grant-funded scientific research plan. By way of example, there are more than 130 such companies in the Zhangjiang High-Tech Park in Shanghai. Generally they are working in high-grade incubator space built with other Chinese government money.

A number of Western researchers with whom I have spoken suggest that many of these scientific projects will never result in serious innovation because many Chinese scientists are not natural innovators but instead, as a cultural matter, prefer to be directed and work extremely hard on given projects. I have to say that I believe this view to underestimate the sheer scale of the scientific endeavour going on in China, which I believe will yield some truly innovative results based on the sheer "shots on goal" principle.

In the present day, many of these small companies are still only undertaking patent filings in relation to China, mainly on the grounds that, in order to get the product on the market in China, a local patent filing is needed. Many of these patent filings are drafted in Chinese by the professor who has made the invention and are nowhere near international standards.

So it is not that patenting is not occurring; it is occurring, but in many cases, inventions by the returnees are not up to an international quality level.

So what do I predict for the medium-term future, 2-5 years hence?

In my view, as these small companies move towards the IND point with their first products and they realise the scale of investment required to fund the early-stage development and the extra skill-sets they need to hire to carry this out, there will be a momentum for consolidation, driven in part by the input of venture capitalists. Indeed, the venture capital market itself amongst these small companies in China in the life sciences sector is likely to see something of an explosion in coming years; witness the many venture funds opening in Shanghai or thinking about opening in Shanghai. The overall level of venture investment in China is still at a relatively low level, being only US$400 million in 2009. This is likely to change as science evolves beyond the point where there can be sole reliance on grant money.

Venture investing in the region will be comparatively attractive for the right company because the Chinese government has launched new grant programs that fund progress towards commercialisation. For example, a recent commercialisation fund initiative has been launched which provides for grant funding for up to $35 million for a particular company, US$10 million for each of three years, sourced 50% from federal funds, 25% provincial funds, and 25% municipal funds. For the venture capitalists, it is possible to build early emerging-stage companies much cheaper in China, particularly when you take into account that the cost of clinical trials can be only 10-20% of the comparative cost in the USA (leaving aside the initial infrastructure investment required to, e.g., build a plant that can manufacture to GMP, this component of the equation really being provided by the infrastructure development in China).

As consolidation and venture investment occurs, there will be a drive towards patenting to international standards and internationally, and then there really will be a seismic shift in the world patent order, due to the sheer number of patents being filed in China, now more than in the USA annually.

The small, fast-growing companies will also drive another important development in China. Because historically early-stage clinical trials such as Phase I trials were generally conducted only for generics in China, there is actually very little real investigator experience in China of running Phase I and Phase II clinical trials to local standards, let alone to international standards. As the demand for these sorts of trials picks up when the INDs are filed and approved by these small, fast-growing, companies investigators will derive highly-valuable experience conducting these trials and so bring China up an important learning curve, removing this key capacity constraint.

Slow IND review times in China by SFDA have caused great tension, and in part have lead to the corruption scandals that have plagued the SFDA. The average time it takes to get IND approval is 15-18 months, and frequently longer. It is predicted this will improve, but there are legal steps a Western company can take to shorten approval times if appropriate investment is made in China.

At the other end of the spectrum to the small returnee lead companies are the indigenous Chinese pharmaceutical companies, often part of some larger conglomerate involving mining, steel, and chemical manufacture. Many of these companies manufacture API, for example. The best of these companies market and distribute very many products in China and have established the complex distribution systems necessary to best penetrate both the urban and rural populations. When questioned about their desire for overseas expansion, the vast majority of these larger companies indicate that right now, with the explosive growth of the pharmaceutical market in China, and the complexities of the

Chinese market, they have their work cut-out addressing their own market, and are simply not really interested in expanding overseas at this point. These sorts of companies are happy to contemplate in-licensing a late-stage product for marketing and distribution in China, but they are extremely uncomfortable about licensing in an early-stage product, having no real experience of early-stage R&D, and are therefore not able to undertake even a basic level of due diligence or development planning for such an in-licensed product.

Generally there is a dearth of companies at the mid-level between the smaller returnee companies and the larger pharmaceutical companies that are part of conglomerates, but to the extent these mid-level companies exist, they can be more adventurous. Although not necessarily prepared to contemplate licensing-in a pre-clinical or Phase I compound, some of them are prepared to consider doing so following Phase II clinical trials. Therefore, one deal model that could potentially find traction is a model where developments up to the end of Phase II clinical trials occur in the West with the results held by the Western rights-holder, and the Chinese local partner then commits to conduct to Phase II clinical trials in China to international standards at its own cost and expense and in return for sharing the results receives the commercialisation rights for China (and possibly manufacturing rights either just for the local market, or for the worldwide market as well). In this way Western companies may be able to begin to leverage their development portfolios as the value of the Chinese commercialisation rights increases.

There is a strong case for medium-sized Western companies to think about entering the Chinese market and to do so with a local partner. Not only are there Chinese regulations prohibiting non-Chinese companies from carrying out Phase I and Phase II clinical trials in Chinese patients (this is circumvented for the very largest pharmaceutical companies by having local operating subsidiaries) but also, with a local joint-venture partner, that partner is likely to more vigorously assert any proprietary position that may exist in relation to the product, and be more successful when doing so, than a foreign organisation.

My broad conclusion is that the internationalisation of the Chinese R&D effort and pharmaceutical industry is probably ten or so years away, but when it occurs, it will likely have a radical impact on world life sciences. I repeat that the sheer scale of the Chinese life sciences undertaking is not to be underestimated. In the meantime, the Chinese market itself, developing rapidly, with the Chinese middle-class expanding and developing Western-style illnesses, represents a golden opportunity for Western companies to leverage potential value in a way that they have not been able to do previously. Those Western companies that accept this can come up with innovative deal-making strategies for the China market and in this way generally improve their own competitive position the most. Although the BRIC emerging markets are lumped together in discussion, I believe commentators like IMS Health are right to carve out China for special attention, as all the evidence suggests that China is many years ahead of its other BRIC competitors.

Contact:

Julian Thurston
+44 20 7920 4050
jthurston@mofo.com

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