

The Rise of China Biopharma

Exploring the prospects—and related challenges—for Chinese life science as it aggressively pursues new growth areas

There has been a great deal of interest in China on the biopharmaceutical and health-care fronts for quite a while and that interest continues to escalate. If you go back in history, it was not long ago that China was principally a low cost, low quality producer of pharmaceutical intermediates and fine chemicals, along with many companies from India. Subsequently, there was a forced clean-up of manufacturing practices that significantly improved the reputation of Chinese-sourced active pharmaceutical ingredients (APIs) and fine chemicals. The Chinese pharma firms were also producers of traditional Chinese drugs and many generic pharmaceuticals for local and international consumption.

Since then, the Chinese have moved up to be more global producers of generic drugs and are beginning to manufacture and even develop more sophisticated medicines, some of which are proprietary to the Chinese biotech or pharma companies. There are even increasing numbers of Chinese biotech and pharma organizations that are conducting clinical trials for drug candidates in China and the US simultaneously.

On the regulatory front, it has been a bumpy road for the Chinese FDA as it struggled to develop and implement standards and approval procedures that were appropriate for the Chinese market and increasingly in line with the US FDA and the European Medicines Agency (EMA). There is increasing respect for the Chinese regulatory system now in

China and abroad. Also, as is the case for the US FDA, the Chinese FDA is trying to streamline its approval process without compromising science and public safety.

In terms of the Chinese health-care market, the attraction of a very large population has always drawn a great deal of interest on the part of both Chinese and Western providers of drugs. China has gone from a system with no healthcare insurance and a hospital-centric healthcare system to the introduction of healthcare insurance and a more diversified, modern system of providing patient care.

Lastly, the Chinese are trying to create the very delicate ecosystem that exists in selected parts of the world that is required to attract leading researchers, develop drugs successfully, establish and fund biotech companies, and provide the providers of capital with the liquidity and valuation increases that are critical to the success of biopharmas in the West.

The history of new drug development ecosystems in various cities and countries around the world has had a very mixed record of failures and successes. The number of regions that have tried and failed is significant. Those that have studied this phenomenon believe that there is a delicate balance of strong research universities; government-sponsored research organizations (such as NIH and DARPA in the US); pharma companies with the right mix of tools and people; funding sources at every stage of product development of a biotech; a regional stock

market that will support emerging biotech; and the right living environment that can attract the best researchers.

China has been working very hard to try to create successful biotech/drug development ecosystems in various locations in China. These efforts include massive funding focused on graduating large numbers of university-trained Chinese scientists, encouraging the growth of venture capital and private equity funds that can invest in Chinese biotech/pharma, and the recent designation of biotech as one of the targeted industries that Chinese wants to achieve an independent major position in by 2025. Other targeted industries include robotics, aircraft, and electric cars.

In addition, the Chinese government changed the rules with regard to IPOs in Hong Kong that allow biotech and technology companies that do not have revenues to go public, subject to certain rules and restrictions, on the Hong Kong exchange. Previously, companies without revenues could not go public in China on any of the exchanges, and the only option for Chinese biotech to go public was in the US or Europe via an IPO or reverse merger. It is not yet clear how many Chinese biotech will go public on the Hong Kong exchange, but there is no question that the public market valuations in China across many industries are substantially higher than those in the West. Whether this is sustainable or not is not clear. However, for the moment, it does give Chinese companies that are public a clear advantage in terms of their cost of equity.

It is not yet certain whether the Chinese government and pharma/biotech community will achieve the targeted goal by 2025 or, more importantly, whether it will be



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able to create successful and stable ecosystems. It is clear that the Chinese are very intent on trying.

Opportunities

The list of opportunities for both Chinese and Western pharma and biotech companies is substantial. To start, the Chinese market for drugs is mushrooming and the incentives to sell existing and new drugs into the Chinese market are high. Although there are pricing, intellectual property, distribution, and regulatory issues to deal with, the overall opportunity is positive, but very much driven by the specifics of each drug and company.

In addition, with many now established Chinese biopharma companies, Western drugmakers

are regularly partnering or licensing product candidates or US-approved treatments with Chinese organizations. The other opportunity is that there are an increasing number of new drugs that are being developed by Chinese companies where the clinical trials and marketing in the US or Europe will be better handled by a Western biopharma company with regional regulatory expertise, in-place sales and marketing resources, and, if needed, funding.

Lastly, although the revision of the Hong Kong Stock Exchange IPO rules will primarily benefit Chinese biotech IPOs, it will also be open for dual listings by Western biotechs, which could enable access to more Chinese investors.

Threats

There are also threats, although the list is not as long as the opportunities. The obvious threat is the potential for Chinese biopharma companies to eventually become aggressive competitors in the more attractive therapeutic areas, aided by government support; looser standards around issues such as the use of genetic engineering; easier availability of private and public equity funding at higher valuations; and the dramatic increase in university research and graduates.

Whether the Chinese can gain significant share over time in the market for more sophisticated drugs is still an open question, but it's clear that its government wants the industry to achieve that goal. **PE**

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