Biopharmaceutical Industry Trends in China—A Five-year Prospective

Now that China has opened its window to the world, its biopharmaceutical industry will see more opportunities

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China's biopharmaceutical industry is entering what some have termed a "Golden Age." The outlook, although generally positive, presents a number of hurdles that may dampen short-term optimism for investors and businesses. But the prognosis, given the current demographic, political, economic, and healthcare situation in China, is positive.

A unique aspect of China's economic planning is its Five-Year Plan, the national economic development guidance that outlines the country's overall development in five-year periods. The plan was established in 1953 when the Chinese central government devised a five-year planning approach to allocate the national resources necessary for construction, development, and economic expansion. The 11th Five-Year Development Guidelines for 2006–2010 follow a logical approach in terms of resource allocation and projections. The central government plans to continue investments in the biopharmaceutical sector to help it become one of the leading industries in China by 2020.

China's National Development and Reform Commission (NDRC) drafted and issued the 11th Five-Year Guidelines for Healthcare Industry in September 2006, based on the national 11th Five-year Plan. The guidelines outline the principle objectives of the Chinese healthcare industry including the following:

- Development and commercialization of 10–15 innovative drugs and vaccines with Chinese-owned intellectual property (IP) rights for the treatment of major, acute infective diseases, or chronic severe diseases.
- Marketing five chemical synthetic finished drugs to US or EU countries.
- The country will foster five large-scale pharmaceutical groups with more than 5 billion RMB sales revenue ($640 million), promote 10 pharmaceutical distributors with over 3 billion RMB sales revenue ($384 million), and help five domestic pharmaceutical enterprises evolve to international enterprises.

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GROWING PHARMA MARKET

Beyond the five-year planning projections, BioPlan Associates developed more specifics regarding biopharmaceuticals. The projections for China's biopharmaceutical industry are based on data and information from the recent study, *Advances in Biopharmaceutical Technology in China*, copublished by BioPlan Associates and the Society for Industrial Microbiology. The study indicates that China's biopharmaceutical sales totaled RMB30.31 billion ($3.9 billion) in 2005 and its 2006 sales are estimated to exceed RMB36 billion ($4.6 billion). Despite the impact of additional drug price cuts mandated by the government, we predict the Chinese biopharmaceutical industry will continue to see moder-

ate growth. Over the next five years, we project a rate of 22%, to 80 billion RMB (~$10.3 billion) through 2010. The primary drivers in the industry will be vaccine and protein therapeutics.

"China's biopharmaceutical industry is now embracing strong development opportunities," said Lifeng Wang, CEO of China National Biotech Group (CNBG) at the First International China Biopharmaceutical Symposium (ICBPS) that was held in Beijing in December 2006. "Chinese biopharma enterprises are looking forward to more collaboration with the world's leading biopharma institutions and companies. We expect to achieve a win-win situation with our global partners. The Chinese biopharmaceutical industry is ready to make significant contributions to global disease prevention and healthcare," she added.

CNBG is the largest vaccine manufacturer in China and controls six biological product research institutes and two manufacturing companies. China's vaccine sector is a bright spot in the biopharmaceutical industry. Because of its population, the country is currently the world's fourth largest vaccine market, following US, Germany, and Japan. As China's population approaches 1.36 billion by 2010 and 1.45 billion by 2020, the country will most likely become the world's largest vaccine market in the future. This change is driven by the market demand, a thriving economy, and an improving healthcare system.

CURRENT SCENARIO

China's biopharmaceutical industry has witnessed 20% to 30% revenue growth annually since 2001. Today, China is home to more than 400 biopharmaceutical manufacturers, including 114 genetically engineered drug manufacturers and 28 vaccine manufacturers. Over 30 domestically produced protein therapeutic drugs and 41 vaccines have been commercialized in China. The country also exports vaccines, recombinant insulin, and other biochemical raw materials.

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Certainly, in the global landscape, the Chinese biopharmaceutical industry remains small-scale, accounting for less than 7% of the world's total biopharmaceutical market. Also, 95% of the Chinese domestic biopharmaceutical market is made up of biogenerics (copies of biotherapeutics developed outside China). The overall innovative capability of the industry today is quite limited. Most manufacturers are very conservative and their investments in product R&D are small, because of lack of capital and venture capital (VC) support. Government funds and grants are not sufficient to subsidize major research projects at biopharmaceutical companies. As a result, Chinese organizations have sought subsidies and investments from banks and other capital markets, both domestic and international. Today, public and university research institutes receiving government funds play a key role in the R&D of biopharmaceuticals.

In addition to producing a variety of biogenerics to supply its domestic market, China has succeeded in developing and commercializing several innovative biotech drugs and vaccines. Some research-oriented Chinese biopharmaceutical companies such as Shanghai Sunway Biotech, Yantai Medgenn, and Beijing Biotech Pharma have developed a handful of novel protein therapeutic drugs. These companies have won grants from the National 863 Program, a Chinese government-sponsored high-technology support program that has funded the R&D of more than 300 new biotech drugs across the country. Beijing Biotech Pharma has attracted foreign investment from a variety of sources, including Cuba, but it has yet to see substantial market penetration for its key product—hR3 MAb.

FUTURE TRENDS

A number of trends are emerging in China, including regulatory, enterprise, and IP. Some of these are outlined below.

Regulatory Trends

Increasing government support

In many countries, government support is one of the most important forces fueling biotech development. The Chinese government emphasizes the biopharmaceutical industry in the 11th Five-Year Plan period. China's National Medium- and Long-Term Science and Technology Development Plan Outline (2006–2020) indicates that in the next 15 years, China will deploy a series of cutting-edge technologies in the biotechnology sector. These include target discovery, animal and plant species and drug molecular design, gene operation and protein engineering, human tissue engineering based on stem cells, and new

Technology Trends

Results of a survey of over 100 senior Chinese experts on the development of China's biopharmaceutical technology. The survey was conducted by conducted by the Tongji Investment Institute. (The trends listed below are according to survey result rankings).

Future R&D focus for biopharmaceuticals

1. Combining imitation and innovation
2. Improving drug forms and indications
3. Tracking foreign novel drug R&D and preemptive drug innovation
4. Imitation of expired patented drugs (generics)
5. Focus on full product innovation

Future R&D modes for new biopharmaceuticals

1. Generic drug development
2. Extensive new drug development (R&D on marketed drugs)
3. Development of new preparations
4. Development of innovative products
5. Innovative drug R&D breakthroughs

Key R&D field

1. Target drugs focused on tumor drugs
2. Blood substitutes
3. Vaccines and enzyme-linked diagnostics
4. Chinese herbal medicines and effective bioactive ingredients
5. Biotech marine drugs
6. Reconstruction of antibiotic production technology
7. Active protein and polypeptide drug
8. Humanized monoclonal antibodies

Key R&D subject (disease type)

1. Malignant tumors
2. Cardiovascular/cerebrovascular diseases
3. Infectious diseases/inflammations
4. Functional degenerations
5. Respiratory system diseases
6. Hereditary diseases
7. Immunological deficiencies
8. Nervous/mental diseases
9. Digestive system diseases
10. Birth-control

generation of industrial biotechnology. The government will also increase investment in biopharmaceutical sectors.

IP protection enforcement

China is making strides in the protection of IP rights in conformity to the WTO requirements. This trend will continue in the future. Several multinational companies have established R&D centers in China. This shows increasing confidence in China's IP protection system. For example, this was a key reason Novartis chose to set up its eighth global R&D center in China in November 2006.

Regulatory reforms

China's State Food and Drug Administration (SFDA) is modifying policies to encourage innovation and restrict imitation. It is also issuing policies to encourage biopharmaceutical outsourcing. Moreover, the country is on the way to establishing an effective VC system to attract foreign venture capital in the biotech sector.

Drug price cuts

The government has conducted 19 waves of drug price cuts and is planning more in the coming years. This may affect the country's biopharmaceutical revenue growth but will benefit the Chinese drug consumers. The overall increase in volume may offset the reduction on per-unit revenue.

Technology Trends

The biopharmaceutical industry is driven by novel technologies to a great extent. A study conducted by the Tongji Investment Institute, based on a survey of over 100 senior Chinese experts, has indicated trends in China's biopharmaceutical technology development.[1] These experts were chosen from CNBG, National Human Genomics Institute, China Disease Prevention and Control Center, Chinese Academy of Sciences, Beijing Fourrings Biopharma, and Triprime Gene, etc.

Enterprise Development Trends

Strategic alliances

Chinese biopharmaceutical companies are forming strategic alliances to enhance their overall strength. For example, China's biopharma giant, CNBG, was formed by merging six major biological product institutes in Beijing, Shanghai, Changchun, Wuhan, Lanzhou, and Chengdu with two biopharma manufacturers (Beijing Tiantan and Chengdu Rongsheng). The resulting organization employs 10,000 people across China. On the other hand, small-to-medium sized biotech com-

To be successful, Chinese biopharmaceutical companies must foster innovation.

panies with one or two new products are collaborating with big companies with strong financial, facilities, and sales network support.

Cluster development

Chinese central and local governments have built more than 100 biopharmaceutical parks across China. Shanghai Zhangjiang High-tech Park is a successful example where more than 100 domestic and international biopharmaceutical companies and central research organizations (CROs) are located including Roche, Novartis Biomedical Research Co., Kirin Kunpeng Biopharma, Wuxi Pharma Tech., Shanghai Lead Discovery, and several others. Despite these successes, however, many of the Chinese high-tech parks continue to have a high vacancy rate and are well below capacity.

Increasing R&D investment and establishing product pipelines

Chinese biopharmaceutical companies are becoming aware of the need for R&D investment and are actively seeking sources of funding for product R&D. Several biopharmaceutical organizations are attempting to establish effective technology platforms to meet the needs from upstream R&D, pilot experiments, and clinical studies, to downstream production. For example, Shenyang Sunshine Pharma, which insisted on investing 10% of its sales income on new product R&D, has been rewarded by the successful development of rh TPO, EPO, and other profitable products.

More international collaboration

With a growing number of overseas Chinese returning to China and taking important positions in Chinese biopharmaceutical companies and institutes, international collaborations are playing an increasingly important role in the community. This has become an important trend in the industry.

Mammalian cell expression drug development

Most of the world's best-selling biopharmaceuticals use mammalian cell culture technology platforms. MAb drugs have become very promising and profitable products worldwide. In China, however, many manufacturers still rely on less expensive *E. coli* technology platforms in production. Relatively few products are produced through mammalian cell expression. It is likely that Chinese biopharmaceutical companies that manage high-efficiency mammalian cell expression technology and scale-up cultivation technologies will be rewarded in the domestic market.[2]

WINDOW OF OPPORTUNITIES

China is projected to become one of the world's major biopharmaceutical players, along with the US, Europe, and Japan over the next 15 years. Now that China has opened its window to the world, its biopharmaceutical industry will see more opportunities. Chinese biopharmaceutical companies must foster innovation. To succeed they must collaborate with the world's leading biopharmaceutical enterprises and strengthen their technologies by integrating domestic and foreign resources. To the extent that Chinese biopharmaceutical organizations follow this approach, they will become a major force in the world biopharmaceutical markets. ◆

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