

China's R&D Industry CONTINUES TO THRIVE

Drug development in the United States and European Union is becoming increasingly expensive and time-consuming. As a result, China has emerged as an increasingly attractive option for companies aiming to reduce prohibitive investments in time and finance. According to a recent report from Business Insights, CROs can reduce research costs by up to 70% when research is conducted in China, and drug developers can expect typical savings of 30%. These cost advantages will continue to encourage

drug developers to conduct clinical trials in China, although preclinical testing is set to become increasingly prevalent as well.

The report, *Drug Development Opportunities in China*, provides a comprehensive review of China's drug development industry, both in terms of R&D for the expanding domestic market and the country's role as a third-party provider of outsourced global drug developments. The report examines the methods of expansion adopted by China's pharma companies, biotech developers, and contract research organizations to increase the scale of their drug development operations, in addition to identifying their therapeutic interests and development cycle focus. It also provides forecasts for drug development trends in China over the next five years.

According to the report, Chinese sales of Western-style pharmaceuticals were valued at about \$13.1 billion in 2006, achieving year-on-year growth of 30%, with the country expected to become the world's leading consumer of pharmaceuticals by 2020. In addition, strong government support continues to drive China's biotech and pharma industries, and will help them to become major components of the global market over the next few years.

The report notes that human clinical studies have historically dominated outsourced R&D activities in China, with the country's relative lack of capital and expertise being insufficient to facilitate technologically intensive discovery and preclinical work. However, an influx of Western-trained scientists and increasing access to global capital markets are rapidly extending the development opportunities available to China's expanding base of pharma and biotech companies.

The report projects that in the near term pharmaceutical R&D for China's domestic drug markets will include a range of products, including generics, medications based upon traditional Chinese medicine, and novel pharmaceutical entities. Generics will continue to comprise a large but declining share, as patent laws are increasingly tightened and most of the leading medicines that would make attractive generics have already been converted, the report says.

Key Trends to Watch

- Increased drug development costs. The price of procuring leading scientists and sophisticated technologies is rising, and this is being reflected in the growth of drug development costs.
- Outsourcing of clinical trials. Growing numbers of clinical trials are being conducted in China in an effort to exploit large, drug-naïve patient populations, at lower costs than in the U.S., Western Europe, and Japan.

- Expansion in size and number of clinical trials. The increase in clinical trials has been prompted by regulators seeking more extensive study data to validate drug safety. Greater numbers of postmarketing Phase IV studies and a rising level of drug development activity have also contributed to this trend.
- Domestic drug market potential. The rapidly expanding Chinese economy and shifts in medical insurance are generating substantial domestic demand for drugs.
- Enhanced scientific capabilities. Large numbers of returning Chinese scientists and expanded access to capital are creating a growing pool of scientific expertise in China.

Biologics DRIVE DOUBLE-DIGIT GROWTH of RA Drug Market

The rheumatoid arthritis treatment market has been held back somewhat in recent years by generic competition and the withdrawals of Vioxx and Bextra. But the category is rebounding because of the performance of immunosuppressants and other biologic treatments, with the market for prescription RA drugs topping \$12 billion in 2006 and expected to grow by more than 11% annually through 2011.

The Kalorama Information report, *Worldwide Market for Rheumatoid Arthritis and Lupus Treatments*, analyzes the current and potential world market and opportunities for prescription drugs to treat RA and lupus.

According to the report, biologic treatments such as Amgen's Enbrel, Genentech's Rituxan, and Centocor's Remicade represented three-quarters of the RA market in 2006. The availability and increased use of biologic drugs have revived growth in the industry, offsetting declines for older nonsteroidal anti-inflammatory drug (NSAID) treatments, which tend to have more generic competition. Sales of biologic treatments will grow 85% by 2011, the report projects.

"Any drug market would suffer from having the world's most well-known drug withdrawal, but biologics are changing the story," says Bruce Carlson, publisher of Kalorama Information. "Biologics show better results than the standard treatments and, in the near-term at least, they won't have competition from generics."

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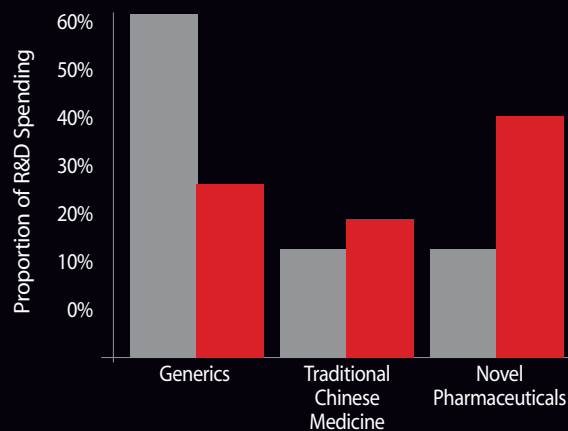


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**PROPORTION OF R&D SPENDING BY
TYPE OF PRODUCT, 2008 AND 2013**



Source: Business Insights, London
For more information, visit globalbusinessinsights.com.

mon biologic approaches to RA involve immunosuppressant drugs that block three actors in the immune system: T-cells, chemical messengers, and white blood cells. The report also discusses novel new therapies that activate suppressor cells, inhibiting the production of inflammation enzymes, suppressing the production of inflammation agents, and preventing the production of B-cell antibodies.

Market for Novel Oncology Therapies LIKELY TO EXPAND AS POPULATION AGES

Cancer causes about 12.5% of deaths worldwide, and is the second-leading cause of mortality in the United States. Since the risk of cancer increases with age, the burden of the disease is projected to grow in tandem with the aging population.

But improvements in the diagnosis and treatment of cancer have increased the chances of surviving the disease. According to a recent study by healthcare investment bank Leerink Swann, the growing number of cancer patients, combined with adoption of novel therapies that command premium pricing, is expected to drive the expansion of the global oncology market in the next decade.

Novel Approaches for the Treatment of Cancer, part of Medacorp Reports' Future in Focus series, evaluates private companies that are developing promising oncology drugs against both new and well-characterized targets.

In terms of already-validated cancer targets, the study notes that two new proteasome inhibitors in development by Proteolix and Nereus Pharmaceuticals aim to challenge Millennium Pharmaceuticals' Velcade by offering improved tolerability and efficacy. Velcade is indicated as a secondary therapy for patients with multiple myeloma or mantle cell lymphoma, and is currently the only FDA-approved proteasome inhibitor on the market.

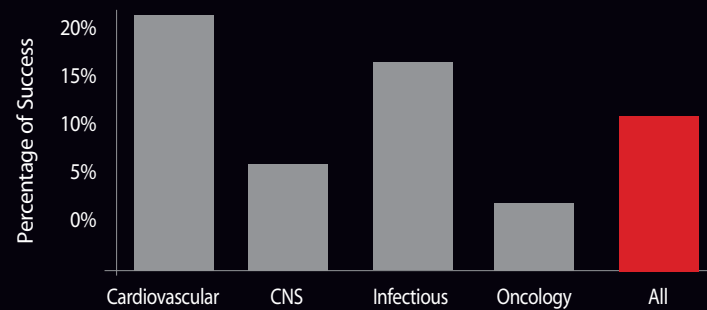
The study also found that Hsp90 (heat shock protein 90) and Bcl-2 inhibitors have the potential to improve the efficacy of standard chemotherapeutics and could work in tandem with some currently marketed agents. Companies investigating these substances include Serenex, which is studying Hsp90 inhibitors; and Ascenta Therapeutics and Gemin X Pharmaceuticals, both of which are developing therapeutics based on Bcl-2 inhibitors. Since publication of the study, Serenex has entered an agreement to be acquired by Pfizer.

According to the report, one of the most promising new delivery vehicles under investigation appears to be the folate receptor-targeted drug, which delivers potent anticancer agents to the tumor with high specificity. This delivery mechanism, which is being developed by companies such as Endocyte, could significantly improve therapeutic efficacy while minimizing side effects. Optimizing patient selection by screening for patients whose

tumors over-express the folate receptor is likely to increase the probability of success of this therapeutic approach, the study says. Among other factors, oncology drugs have one of the highest attrition rates in the pharmaceutical industry, with an estimated 95% of anticancer drug candidates failing in clinical development.

Compared with other therapeutic areas, oncology drugs' failure rates underscore the poor predictability of animal models. Improving this predictability is one possible method for reducing attrition and boosting success rates of oncology drugs.

CLINICAL SUCCESS RATE OF DRUG CANDIDATES IN SELECTED THERAPEUTIC CATEGORIES



Source: Leerink Swann, Boston. For more information, visit leerink.com.

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