Kim Ribbink

NI HAO CHINA:

A *Booming* Market Takes its Place *on the* WORLD STAGE

In the second installment of our global series, PharmaVOICE visits the world's most populous nation, China, which has become a must-destination — on all levels — for pharmaceutical companies.

Whether it is partnering, acquisitions, or the expansion of operations, China spells opportunity for the pharmaceutical industry.

Increasingly, global pharmaceutical companies are either expanding their own operations within China or choosing to partner with China-based companies.

According to IMS Health, China is expected to become the world's third-largest prescription drug market in 2011 and the second largest by 2020. The industry is growing significantly, with statistics from the Ministry of Industry and Information Technology showing value-added output of China's pharmaceutical industry increased 14.9% year on year in 2009.

There are numerous growth drivers responsible for China's emergence as a top pharmaceutical destination, Kantar Health experts say, including favorable government policies to increase healthcare spending and expanding reimbursement coverage; robust end-user demand for medical care, including generic and innovative therapeutics, devices, diagnostic tests, and accessible healthcare services; and increasing private reimbursement and middle-class affordability.

FACT

THERE IS A SIGNIFICANT SAVINGS ON OVERALL CLINICAL TRIALS, SINCE THE COST OF CONDUCTING TRIALS IN CHINA CAN BE ABOUT ONE-THIRD OF THAT IN THE U.S. DUE TO LOWER PER-PATIENT COSTS.

Source: Parexel International

"Favorable government policies are increasing healthcare spending and expanding reimbursement coverage," says Adele Li, head of marketing insights at Kantar Health's Shanghai office. "Also, healthcare accessibility is accelerating and efficiency and quality were identified as the key objectives of China healthcare reform from 2009 to 2011. The expansion of reimbursement coverage and increasing government funding will drive China's pharma market growth at the same time multilayer price management and prescription restriction will slow the trend."

Furthermore, underinvestment and inequitable distribution of resources in China's fragmented, hospital-led healthcare system have contributed to wide disparities in healthcare provision between eastern and western provinces, urban and rural populations, and among income groups.

All of these factors are helping to drive robust demand for medical care, including generic and innovative therapeutics, devices, diagnostic tests, and accessible healthcare services.

Companies are also capitalizing on opportunities to expand their operations in China, helped in part by the high caliber of local personnel. According to Jeanie Kwon, senior director of regulatory operations at Image Solutions (ISI), China has the largest number of engineers, science postgraduates, and Ph.D.s

> "We see the long-term potential in China and are continuing to invest in R&D efforts."
>
> **JOE JIMENEZ** / Novartis

> "Virtually all major drugmakers have targeted China as a critical area for future growth."
>
> **NICK COLUCCI** / PHCG

Upcoming Conferences

- **2nd Annual Biomanufacturing and Single Use Systems Asia**
  March 7 - 9, 2011
  Sheraton Hotel Shanghai, Shanghai
- **3rd Annual World Pharmaceutical (China) Summit 2011**
  March 17 - 18, 2011
  Shanghai Pudong, Shanghai
- **6th International China Pharmaceutical R&D Summit**
  April 11 - 13, 2011
  Grand Hyatt Hotel, Shanghai
- **U.S.-China Pharma: Innovative Strategies and Partnership Models for R&D**
  May 23 - 24, 2011
  Philadelphia
- **CPhI China**
  June 21 - 23, 2011
  Shanghai New International Expo Centre, Shanghai
- **BIO China International Partnering Conference**
  October 12 - 13, 2011
  Shanghai

in the world from their numerous academic institutes each year.

The Chinese government is also offering strong incentives to nurture the domestic biopharmaceutical industry, including tax relief, funding opportunities, and the emergence of technology and biotech parks.

Novartis CEO Joe Jimenez says the Chinese government is dedicating resources and providing more incentives to encourage businesses to invest, including establishing a so-called Medicine Valley in Zhangjiang and building a strong biomedical industry in Shanghai.

On a clinical-research level, faster subject recruitment, cost-effectiveness compared with Europe and the United States, and standards that compare favorably to the U.S. and Europe, make China an attractive prospect, says Zhong Chongyu, general manager of Ethypharm in China.

The Health Environment

Urbanization, an aging population, and changing disease patterns are triggering health concerns in areas such as diabetes, cancer, infectious disease, and asthma.

"China already has the largest diabetic population in the world, estimated at 92 million people today and growing at 16% per year," says Mandy Chui, practice leader, pricing and market access, IMS Health Consulting, Asia Pacific.

According to Nick Colucci, president and CEO of Publicis Healthcare Communications Group, a review of 10 Chinese companies' research portfolio shows inflammatory diseases, metabolic disorders, and cancer are the top three therapeutic areas.

More extensive clinical research will help to address these diseases, says Albert Liou, corporate VP and general manager, Asia/Pacific, Parexel International.

"There is also a high prevalence of gastrointestinal cancers, hepatitis, nasopharyngeal cancers, neural tube defects, and nonsmokers with EGFR mutation," Mr. Liou says. "Unique gene pools among the Chinese population are beneficial to pharmacogenomic studies."

Other major therapy areas include anti-infectives, central nervous system, chronic obstructive pulmonary disease, rheumatoid arthritis, psoriasis, osteoarthritis, ulcerative colitis, and atherosclerosis.

Costs for preclinical and clinical research activities in China are expected to remain well contained for the foreseeable future, which should allow companies to make significant inroads into exploring these therapeutic categories.

"Also, the large patient population and concentrated clinical centers allow for easier

China: Healthcare System Fast Facts (2005 – 2009)

» Population	1.34 billion
» No. 1 cause of death	Cerebrovascular disease
» Average Life Expectancy	73
» Total Healthcare Spending	$230.7 billion
» Healthcare Spending per Capita	$172
» Out-of-Pocket Spending per Capita	$90
» Government Healthcare Budget	$66.4 billion to $87.8 billion
» Physician Density (per 10,000 people)	14.2
» Percentage of Patients with Private Insurance	18.8%
» Percentage of Patients with Partial Insurance	18.8%

Source: Cutting Edge Information.
For more information, visit cuttingedgeinfo.com

The Health Landscape

Sweeping healthcare reforms in China are set to bring medical insurance coverage to 90% of the population.

Reforms will establish nationwide, uniform services and improve management capabilities to handle public-health issues, says Nick Colucci, president and CEO of Publicis Healthcare Communications Group (PHCG).

"Additionally, healthcare reform will provide for primary healthcare services, including the development of a primary care network over three years and the restructure of healthcare resources, operational mechanisms, and financial assistance," he says.

The push for change began in 2005 after a State Council report found great disparity in access to care throughout the country.

Novartis CEO Joe Jimenez says there has been significant progress in patient access to healthcare in China, largely due to the government's robust efforts to expand health insurance coverage and access to millions of citizens.

"We're active in supporting the improvement of health and health-awareness education throughout the country, even in remote provinces," he says. "For example, early this year Novartis launched the Jian Kang Kuai Che or Health Express initiative, which aims to meet the unique patient needs of citizens in the rural area of Xinjiang province."

China's largest province, Xinjiang has significant medical needs, given its poor infrastructure and very little access to medicines and health information.

"Our Health Express program has four pillars, which include: teaching hygiene and health education in primary and middle schools; supporting local academic institutions' public health research; sponsoring trainings for local healthcare professionals on infectious diseases to improve diagnosis and treatment; and expanding access to our pharmaceutical, generic, and OTC products for diseases with high-patient need in Xinjiang," Mr. Jimenez says.

Access to healthcare across the country varies widely, experts say.

"In the rural areas, access is still a much bigger issue and the demand is for essential drugs like antibiotics," says Friedhelm Blobel, Ph.D., CEO and president of SciClone. "In the high-growth areas, the adoption of Western lifestyles leads to many Western diseases, such as cardiovascular disease, various cancers, etc."

Despite a growing demand for products and the government's medical insurance initiatives covering a majority of the population, the out-of-pocket costs for patients remains high for innovative drugs because they are not included on the reimbursement drug list.

"The majority of the population cannot afford expensive, innovative drugs, such as targeted cancer therapies; the disposable household income of a top 10% income family is 46,826 renminbi (RMB)," says Adele Li, head of marketing insights at Kantar Health's Shanghai office.

In fact, 50% of drug expenditures are still paid out of pocket by patients, says Mandy Chui, practice leader, pricing and market access, IMS Health Consulting, Asia Pacific.

Editor's note: 1 Chinese Yuan Renminbi = 0.1511 U.S. dollars.

"China is attractive for clinical development because of its large patient population, cost-effective environment, and expanding medical infrastructure."

ALBERT LIOU / Parexel International

"R&D divisions in China help establish the necessary relationships to stay ahead of the curve."

JEANIE KWON / ISI

"Accelerating healthcare accessibility, efficiency, and quality are the key objectives of China healthcare reform."

ADELE LI / Kantar Health

"Market access challenges include pricing, reimbursement, hospital bidding, and listing."

MANDY CHUI / IMS Health Consulting, Asia Pacific

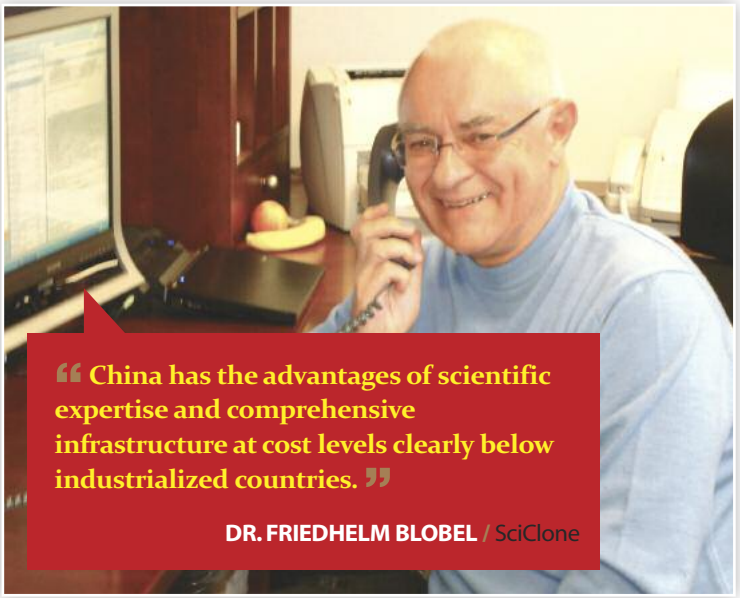
and faster patient enrollment," ISI's Ms. Kwon says.

Product Focus

China is typically not the country to be considered for first to market when it comes to introducing first-in-class therapeutics, says Friedhelm Blobel, Ph.D., CEO and president of SciClone Pharmaceuticals.

"The top-selling drugs are quite mature, which corresponds to slow and steady growth over the years," he says. "But, with improved intellectual property protection for innovative drugs and government action to support novel therapeutics, this will change soon."

Innovation in the Chinese market is taking place in three areas, Mr. Chongyu says: sub-



> "China has the advantages of scientific expertise and comprehensive infrastructure at cost levels clearly below industrialized countries."
>
> **DR. FRIEDHELM BLOBEL** / SciClone

> "The biggest challenge to conducting clinical research in China is timing."
>
> **ZHONG CHONGYU** / Ethypharm

stance innovation, the business model, and drug delivery solutions.

Mr. Chongyu notes that while regulatory officials are supportive of innovative drug delivery solutions, the current application system only incorporates bioequivalent studies, which don't always show predicted results.

"For example, Flashtab, an innovative drug delivery solution, is well-accepted in the international market, but not in China," he says. "We need to develop a shared definition of innovative drug delivery solutions, and switch the focus in China from thinking solely about compound innovation to embracing drug delivery solutions."

When it comes to product promotion in China, Mr. Colucci says companies must think carefully about how to reach out to the thousands of village clinics and township health centers, and how to choose the best commercial model to engage with the various stakeholders in the system.

"A combination of innovation and distribution expertise is needed to help meet access demands," he says. "Further, the cultural, socioeconomic, and geographic diversity of the consumer population, in conjunction with government review policies, presents a complex framework for the development of cost-effective consumer campaigns."

Best practices from other established markets are helping to inform marketing decisions, with companies leveraging an integrated array of online and offline media, PR/events, peer-to-peer communications, medical education, and both personal and non-personal sales channels in their brands' promotional activities, Mr. Colucci says.

"And as in the rest of the world, companies operating in China — the leading mobile market in the world, with an estimated 800 million mobile phone users, according to Euromonitor — are also exploring the potential for mobile health to strengthen marketing efforts," he says.

There are a lot of opportunities for companies to establish a recognized presence, Dr. Blobel points out.

PODCAST

CHINA: An Emerging Market for Cancer Therapeutics
THOUGHT LEADER: Richard Wagner, Ph.D., Senior Director, Kantar Health

"The value of a pharmaceutical brand in China is on par or even ahead of IP protection, and certainly much more important than in western countries," he says. PV

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China's Regulatory CLIMATE

With China growing as a market, both in terms of clinical research and product submissions, companies need to be cognizant of the challenges that lie ahead.

According to a recent Thomson Reuters study, Global Research Report: China, over the past several years, there has been explosive growth in research output from China, far outpacing research activity in the rest of the world. At this pace, industry observers predict that China will overtake the United States in research output within the next decade.

The Thomson Reuters study found that China's output increased from just over 20,000 research papers in 1998 to almost 112,000 in 2008, surpassing Japan, the United Kingdom, and Germany and now standing second only to the United States. China's research is concentrated in the physical sciences and technology, with materials science, chemistry, and physics predominating. Thomson Reuters' analysts predict that there will be rapid growth in the agricultural sciences and life-sciences fields, such as immunology, microbiology, and molecular biology and genetics.

"If China's research growth remains this rapid and substantial, European and North American institutions will want to be part of it," observes Jonathan Adams, director of research evaluation at Thomson Reuters. "China no longer depends on links to traditional G8 partners to help its knowledge development. When Europe and the United States visit China, they can only do so as equal partners."

As research output continues to accelerate in China, the next hurdle is having the research accepted by regulatory authorities.

Jeanie Kwon, senior director of regulatory operations at Image Solutions (ISI), says when it comes to regulatory practices in China, they are similar to those of western authorities, where compliance is not always black and white with well-written requirements published.

"Although there are policies and guidelines in place, there are on-going advances and changes from the SFDA and the provincial agencies," she says, adding that approvals for clinical trials and drug applications can be a lengthy process.

The SFDA is the State Food and Drug Administration, which was founded on the basis of the State Drug Administration. The SFDA is directly under the State Council of the People's Republic of China, which is in charge of comprehensive supervision on the safety management of food, health food, and cosmetics and is the competent authority of drug regulation in mainland China.

It is advisable, Ms. Kwon says, to work with experienced regional operating companies with knowledge of China's regulatory system.

Experts in the region say preparation is essential. When it comes to conducting clinical research in China, for example, a drug must be first approved in the manufacturing country or be in Phase II or III in another country before trials in China can commence.

"Before conducting clinical trials in China, sponsors must submit the clinical protocol and related documentation and have it reviewed and approved by SFDA before the trial can be started, since unlike in the United States, written approval is required," Ms. Kwon says.

She warns that protocol approval can take as long as 7 to 12 months.

Thereafter, sponsors must submit an annual report regarding the developments on the clinical trial. A clinical trial should start within three years of approval.

Otherwise, the approval certificate becomes null and void and companies must reapply.

As part of the NDA registration dossier, hard copies of the final clinical study report, statistical analysis report, final protocol, ethics committee approval, investigator brochure, and original chromatography of pharmacokinetics test should be delivered to the SFDA. Datasets of the clinical trial need to be provided electronically at that time as well.

"Following the submission of NDA data to SFDA, an onsite inspection of the investigators will be arranged, with approximately four to five sites being selected among all investigators," Ms. Kwon says.

Ms. Kwon says the SFDA has its own submission guidelines with regard to how product submissions are made.

Companies must submit documents in hard copy, although the agency is accepting a combination of electronic and paper submissions, with specific portions required electronically.

Companies can submit in the CTD format for imported drugs, though translation to Chinese is required for all submission content. The requirements for chemical drugs, Chinese traditional medicine, and biological products are defined separately.

Ms. Kwon says while imported drugs need only be reviewed by the SFDA, domestic drug applications must be reviewed initially by the local agencies before being sent for approval to the SFDA.

"The review process at SFDA is not yet fully electronic and can be time consuming as there are multiple levels of review by different departments within SFDA for administrative and technical reviews," she says.

There has been some progress on a regulatory front, including the signing of the Tri-

Investing in China

In the past year, several leading pharmaceutical companies, CROs, and service providers have made an investment in China. Below are selected partnerships, M&A activities, and new facility openings.

» **ABBOTT** opened the Abbott Asia-Pacific Nutrition Research & Development Center at Singapore's Biopolis Research Park. The center is Abbott's largest nutrition R&D facility outside the United States, as well as Singapore's first nutrition R&D site creating science-based nutritional products for infants, children, and adults. The center marked Abbott's third expansion in Singapore in the last two years.
For more information, visit abbott.com.

» **CHARLES RIVER LABORATORIES** acquired WuXi PharmaTech, an R&D outsourcing company in China and the United States. The combined company, which retained the name Charles River, offers a portfolio of products and outsourced services to multinational pharmaceutical, biotech, and medical-device companies and academic and government institutions.
For more information, visit criver.com.

» **CHILTERN INTERNATIONAL** announced expansion plans in the Asia-Pacific region, including the opening of operations in Singapore, which will act as its hub in Southeast Asia.
For more information, visit chiltern.com.

» **I3** acquired ChinaGate, a Shanghai-based CRO that provides regulatory services for pharmaceutical, medical-device, and biotech companies looking to enter the Chinese market. The acquisition gives i3's customers access to ChinaGate's on-the-ground presence and expertise in overseeing clinical trials, submitting filings, obtaining licenses, and navigating the regulatory process in China.
For more information, visit i3global.com.

» **ICON CENTRAL LABORATORIES** opened a laboratory facility in Tianjin, China, in partnership with Fountain Medical Development (FMD). Icon Central Laboratories China delivers site-support services to clinical investigators throughout China. The Tianjin facility is the third such laboratory in the Asia-Pacific region. Icon also signed an alliance with TigerMed Consulting, a provider of clinical drug development services in China. Through this agreement, Icon and TigerMed are collaborating to offer pharmaceutical and biotech clients better access to Chinese patients. With headquarters in Shanghai, TigerMed currently operates from 21 offices in China and has more than 300 clinical development staff there.
For more information, visit iconplc.com.

» **IMS HEALTH** expanded its IMS Oncology Analyzer to additional cities in China, enabling pharma clients to assess treatments and guide commercial decisions in the country's fast-growing $1.5 billion-plus oncology market. The market assessment tool now covers 12 Tier 1 and Tier 2 cities in China, providing a clinically comprehensive view of cancer care from first diagnosis forward and facilitating critical market research insights for areas such as product adoption, dosing and regimen compliance, and market sizing.
For more information, visit imshealth.com.

» **KANTAR HEALTH** expanded its CardioMonitor cardiovascular and diabetes patient database service into Japan and China. The new service helps companies size opportunities, identify treatment dynamics, position products, and sharpen forecasts in the growing Japanese and Chinese markets.
For more information, visit kantarhealth.com.

» **KENDLE's** affiliate in China, Beijing KendleWits Medical Consulting Company (KendleWits), obtained ISO 9001:2008 certification from the International Organization for Standardization, validating the quality and consistency of its operations in this growing region. Through KendleWits, Kendle is the first global CRO to achieve ISO 9001:2008 certification in China.
For more information, visit kendle.com.

» **MERCK SERONO**, a division of Merck KGaA, established a global R&D center in Beijing to lead drug development for China and other Asian countries. The Merck Serono China team is also responsible for managing Merck Serono's collaborations with research institutions in China and continuing to look for partnerships with local academic institutions and companies.
For more information, visit merckserono.com.

» **NEW MOMENTUM**, a provider of SaaS-based anti-counterfeiting, signed a strategic partnership agreement with Sunfaith, a Chinese consulting firm focused on intellectual property protection and market research.
For more information, visit newmo.com.

» **PAREXEL INTERNATIONAL** opened offices in Chengdu and Guangzhou, China. Parexel's existing presence in China includes offices in Beijing and Shanghai, as well as Kowloon, Hong Kong.
For more information, visit parexel.com.

» **PPD** opened a vaccine clinical research center in Taizhou, China. Through the center, PPD will provide clinical monitoring services to global and local biopharmaceutical companies seeking to develop vaccines in China. PPD also expanded its presence in China through the acquisition of Bio-Duro LLC, a Beijing-based drug discovery outsourcing company that provides a broad range of integrated services to biopharmaceutical companies. The acquisition brought PPD's total staff in China to almost 1,000.
For more information, visit ppd.com.

» **QUINTILES** has added data management services into its Shanghai location, strengthening its capability to serve customers in China and throughout the Asia-Pacific region. In addition to its Shanghai operations, Quintiles China has offices in Beijing and Hong Kong. Quintiles also - announced the availability of anatomic pathology services through its central laboratory in Beijing, aimed at helping biopharmaceutical companies develop more effective cancer treatments.
For more information, visit quintiles.com.

» **The REGULATORY AFFAIRS PROFESSIONALS SOCIETY** is collaborating with the University of Shanghai for Science and Technology in China to develop regulatory education content.
For more information, visit raps.org.

Source: PharmaVOICE

partite MOU agreement with Japan and Korea on a joint collaboration to explore the potential of ethnic similarity with an end goal of mutual acceptance of clinical data in the future, says Albert Liou, corporate VP and general manager, Asia/Pacific, Parexel International.

"This effort will continue to greatly facilitate the simultaneous conduct of global and regional product development," Mr. Liou says. "Additionally, the establishment of the U.S. FDA in China will continue to increase the communication between the mutual authorities and will drive the improvement of Chinese regulations."

Other areas of complexity for companies lie in pricing and reimbursement, with a wide array of stakeholders and huge variations of implementation at the provincial level, says Mandy Chui, practice leader, pricing and market access, IMS Health Consulting, Asia Pacific.

"Substantial company resources are required to maintain price, get onto national and provincial drug reimbursement lists, win the provincial bidding, and get listed in local hospitals," she says

Company Activity

On an M&A front, the China Securities Regulatory Commission (CSRC) announced that it will strengthen capital markets to support increased merger and acquisition activity, and many analysts believe that M&A will increase in industries once only accessible to state-owned enterprises, bringing in a large number of foreign investors.

Certainly, global pharmaceutical companies are showing increased interest in China-based entities. In December 2010, GlaxoSmithKline agreed to buy Chinese urology and allergy specialist MeiRui Pharma, while in October, Sanofi-Aventis announced it had agreed to acquire BMP Sunstone, a specialty pharmaceutical company focused on pediatric and women's healthcare products in China.

Partnership is also being sought with China-based companies to advance R&D. Bristol-Myers Squibb signed an agreement with China's Simcere Pharmaceutical Group to co-develop BMS-817378, a preclinical small molecule MET/VEGFR-2 inhibitor, as an anti-cancer treatment.

Novartis has more than 20 ongoing collaborations with universities and hospitals in China.

"For example, we have a joint post-doctorate program with Fudan University, where scientists in the Novartis-Fudan Joint Research Laboratory study cancer genetics and cell biology and develop innovative disease models," says Joe Jimenez, CEO of Novartis. "We have also been working with Chinese partners since 1994 to develop our malaria treatment Coartem."

And many companies are expanding their own R&D operations in China.

Ms. Chui says before 2000, R&D from multinational corporations was mainly driven out of corporate headquarters with minimal amounts of early-stage cooperation with institutes and local companies.

"In the last five to 10 years, with the emergence of some foreign and home-grown chemical and clinical CROs, multinational companies have been getting more viable, low-cost drug development options and starting to invest more heavily in the R&D space," she says.

AstraZeneca, Pfizer, Merck Serono, GlaxoSmithKline, Sanofi-Aventis, and Johnson & Johnson, have announced R&D investments in the order of $50 million to $200 million in the next three to five years, Ms. Chui says.

Perhaps most notable is Novartis, which is investing $1 billion to expand and upgrade its Shanghai laboratory facilities called the China Novartis Institute for BioMedical Research (CNIBR) in Shanghai. CNIBR will become the largest pharmaceutical R&D institute in China, and the third-largest R&D center for Novartis globally.

"The institute will focus on stem cells, epigenetics, and virally induced cancers that are endemic in China," Mr. Jimenez says. "Also, since rates of disease can vary across a country, we are conducting research in particular regions where certain diseases are most prevalent. For example, Hepatitis B is endemic in parts of China and is almost 14% more prevalent in the Guangdong province than it is in the rest of the country." PV

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