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## Feature Article

# Cautious Optimism Prevails for Chinese Biotechnology

## Government's Commitment and Return of "Sea Turtles" Buoy the Industry

Gail Dutton



**BioDuro is a U.S.-based**

**outsourcing services company with a team of over 550 in Beijing. The firm specializes in medicinal chemistry.**

The Chinese word for "crisis" is composed of two characters—one for danger and one for opportunity. That analogy sums up, not only the current global situation, but the situation for biotechs in China too, according to speakers at the recent "Pacific Forum on Life Science Alliances," sponsored by the [Sino-American Biomedical and Pharmaceutical Professionals Association \(SABPA\)](#).

The tainted milk scandal in 2008 is a good example, according to C.J. Wang, Ph.D., vp of business development for [Vivus](#). Stressing that these are only his personal views, he said, "the tainted milk disaster was bad, but it was also an opportunity. In its aftermath, instrument sales surged. Firms used to have difficulty selling their expensive instruments in China. Now, orders come in large quantities," to allow companies to perform food analyses. But, Dr. Wang emphasized, "You have to be there to really understand the market and see the opportunities."

The need to be there is based upon the simple fact that China is changing rapidly. The prescription drug industry has grown 10 to 15% annually since 1979, with revenue projected to reach \$24 million by 2010, according to Zhu Shen, Ph.D., CEO of [BioForesight](#) and vice chairman and board member for SABPA. Consolidation of Chinese biotechs is likely. “We will see some major players emerge,” Dr. Shen predicted. Within China, “leading CROs are moving inland,” she said, expanding their geographic reach and access to talent. Dr. Shen also predicted that “the West will dramatically increase its outsourcing in Asia. Those who anticipate and manage well will win.”

Companies considering outsourcing to China or developing partnerships or other ventures in that nation need to do so in a global context. “You need a global strategy that’s cost effective and can be implemented,” according to Noel Gillespie, partner, [Baker & McKenzie](#). Firms also need to realistically assess the strengths and weaknesses inherent in such agreements and, importantly, the ramifications upon later product development, patentability, and licensing such as: where clinical trials are best conducted, where the initial patents should be filed, and reimbursement strategies. These must be well understood.

Presenters, many of whom recently were in China, noted the energy among scientists, as well as on the streets. Much of that energy is directed toward biotech. Presenters suggested that “Made in China” will, within the next five to ten years, become “Discovered in China.”

Two key factors are contributing to that sea shift. Perhaps most importantly, the Chinese government is determined to develop its expertise in biotech. The nation is committed to competing in terms of intellectual innovation, technological innovation, and high-tech industrialization, Charles Wessner, Ph.D., director of technology, innovation and entrepreneurship at the [U.S. National Academies](#), explained. It is investing in education, infrastructure, and worker training to develop a critical mass. It also is working to

get its message to the right people through such venues as this conference, as well as working with public relations representatives to promote the modern business climate in China. That said, Dr. Wessner stressed that “it’s important to distinguish between trends and what’s already there.”

Another big factor is the return of what China calls “sea turtles”—overseas Chinese who are returning to their home country to work in (and direct) high-tech endeavors. These professionals have experience with good manufacturing practices and good laboratory practices, as well as their intellectual expertise. And, they are fluent in English and have a good understanding of their Western customers.

That combination of factors is resulting in successes. [BioDuro](#), a multinational life science outsourcing company with labs in Beijing, is a prime example. With a staff of 540, one-quarter of its scientists hold doctoral degrees. It has worked with some 40 biopharmaceutical companies, focusing on the hit-to-clinic stage, according to Yun He, Ph.D., vp of research for BioDuro.

[Medicilon](#) has codeveloped, manufactured, and tested compounds successfully and expects to implement good laboratory practices by 2009, according to Jintao Zhang, Ph.D., CEO. [Wilmington Pharmatech](#) has made 44 drug candidates, and conducts process research to optimize reactions for scale-up, reported Harry Hui-yin Li, Ph.D., CEO.

Most of the deals in China right now are in contract research, according to James Schaeffer, Ph.D., executive director of [Merck & Co. Dr.](#) Schaeffer is responsible for Merck’s scouting efforts in China; he considers external alliances a key strategic component in advancing the business. To that end, Dr. Schaeffer is looking for deals with “top-notch laboratories and companies doing basic research,” and for companies with the best organizations for taking compounds from protected targets through Phase I research.

Chinese CROs are responding to that shift of focus. Firms like [Sundia Meditech](#), founded four years ago, built its reputation on contract research. Now, “the landscape is changing,” noted Shawn Shi, Ph.D., executive vp. “We’re trying to build a one-stop shop.”

Sundia Meditech isn’t alone. According to Dr. Shen, CROs are expanding and adding new services, including engaging in mergers and acquisitions, participating in cross-Pacific joint ventures, and forging strategic alliances. While China’s strength remains in basic research, it is expanding its focus to include the diseases that tend to affect affluent populations such as cancer and diabetes.

### Effect of Credit Crisis

“The Chinese government has invested heavily in life sciences,” Dr. Shen said. Also, corporate venture capital firms like [Lilly Asian Ventures](#) are being established. Other venture capital companies are creating Asian funds, and even those not traditionally associated with healthcare are interested in Chinese biotech, she continued.

To some extent, China expects to benefit from the growing outsourcing trend that is catalyzed by the global financial squeeze. In terms of how the credit crisis continues to affect development of small pharmaceutical and life sciences companies in China, “the venture capital (VC) industry has two views,” emphasized Paul DeRidder, M.D., Ph.D., venture partner at [Crystal Cove Capital](#).

One has to “be very, very careful. A lot of firms are keeping their money very close at hand to fund their portfolio companies. Others are trying to get money out to the market.”

Outsourcing is not a panacea, however. “In the near term, we will see continued loss of faith from institutions and high net-worth individuals,”

predicted Dr. Shen. However, she continued, “in China, although the economy is not that tightly linked with what we have here, we are seeing the affect on Chinese economics in the lower value-added sectors, so there will be a struggle.” She suggested that now is a good opportunity for Chinese companies to invest in the U.S.

That view was reiterated by Ding Ding, Ph.D., senior equity analyst, China Healthcare, [Susquehanna Financial Group](#). The effects of the credit crisis on an individual company, she explained, “depend on the makeup of its revenue source: China domestic or international. There are opportunities for strategic alternatives including mergers and acquisitions. For companies or investors who are not constrained by liquidity, it’s a good time to shop.”

“There could be great opportunity,” Dr. DeRidder said. Citing a survey of 400 venture capital firms conducted by Deloitte earlier this year, he notes that 57% of U.S. VC firms will invest overseas in 2008. The interest in foreign investment holds for other nations, too. “The more money you have, the more likely you are to invest outside your country,” he summarized. In terms of destinations, China attracted the largest interest, at 34%, followed by India, Canada, the U.K., and Israel. In terms of attracting capital “Seventy-eight percent of the money invested in China came from foreign investment dollars,” Dr. DeRidder added.

## New Models



**Medicilon was founded in 2003 to provide custom drug discovery**

In addition to the standard opportunities associated with outsourcing, deals in Asia have an added benefit in terms of how a deal is structured. Companies are looking for risk-sharing deals. “Many multinational companies are looking to partner with a local company to help share more of the risk and reward of drug development,” according to Joshua Berlin, executive editor and senior publications manager for [F-D-C Reports](#).

Often, this means having the Asian company develop a compound through proof of concept and then letting the

**services. It has an 85,000-sq-ft R&D facility in Shanghai and also maintains lab space in Chicago.** multinational take over. “It’s a step up the value chain for companies in Asia, and they generally will have more favorable deal terms, because they are taking on more of the risk by funding some of the early-stage development.”

Another model that’s becoming popular involves virtual networks. Essentially, a firm will outsource a project to a local company, which then coordinates further outsourcing among a network of similar companies. The result is a network that forms and reforms around needed expertise. Virtual networks are being embraced by [Merck](#), [Eli Lilly](#), and others.

## IP Concerns

Perhaps the greatest concern for companies considering operating in China is related to intellectual property protection. Until relatively recently, Western companies did not file Chinese patents, feeling they were unenforceable. Today, the situation is getting better. “We’re advising our clients to file patents in China now,” Gillespie said. (See related article: Update on Patent Law Revisions in China on page 10.)

Although attorney Peng Chen, Ph.D., partner, [Morrison & Foerster](#), reported that China is working to harmonize its intellectual property laws with those of the West, some significant differences remain. Therefore, it’s vital to understand the disparities between the Chinese patent and legal systems and those of the U.S. or EU.

There are three types of patents in China, according to Gillespie: the invention patent, which is similar to a U.S. utility patent; a utility patent; and a design patent. “Design patents don’t get examined. They’re really just a registration,” explained Dr. Chen, but this is the type of patent filed most often by Chinese companies. It takes less time to file and is being used to outmaneuver companies that neglect it in favor of filing invention or utility patents.

A European electrical components firm learned this the hard way. While the firm was awaiting review of an invention filing, a Chinese company filed a design patent. Consequently, the electrical manufacturer did not receive its patent, and the Chinese firm proceeded to develop it, winning the subsequent lawsuit. To put the danger into greater perspective, Chinese companies filed 253,675 design patents, versus the 13,993 design patents filed by foreign companies.

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