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## Sending biotech research to China

**A San Diego firm is setting up a lab in Asia to save on costs.**

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SHANGHAI — Donkey meat with garlic juice and deep-fried duck bills aren't Dajun Yang's favorite fare. But while accompanying two U.S. colleagues on a recent trip to Beijing, he made sure they were exposed to cuisine they couldn't find back home.

Culinary tour guide is just one of Yang's many unofficial jobs. As the head of the China subsidiary of San Diego-based Ascenta Therapeutics Inc., Yang also is responsible for staffing the company's new lab in Shanghai, vetting animal-testing facilities and helping colleagues navigate China's regulatory jungle.

Yang's ability to bridge the two cultures is crucial to Ascenta's big gamble: creating a new breed of biotech start-up that marries U.S. and Chinese scientific talent with China's cheap labor and resources. The firm is using technology licensed from the National Institutes of Health and the University of Michigan, where Yang and Ascenta co-founder Shaomeng Wang, both natives of China, conduct their research.

Ascenta is betting that its China subsidiary, which employs 20 scientists working for a fraction of what they would be paid in the United States, will drastically reduce the price tag — and time — of bringing its promising cancer-fighting medicines to market. Investors apparently agree. In April, the company announced it had raised \$50 million, bringing its total funding to \$85.5 million.

If Ascenta succeeds, biotech experts predict it could chart a new path for global drug development, helping China in its bid to leapfrog India and Eastern Europe, the current favorites for drug research outsourcing.

Ascenta is "essentially leveraging the best that both countries have to offer," said Greg Scott, a San Diego investor and editor of industry newsletter ChinaBio Today, who recently opened an office in Shanghai's Zhangjiang High-Tech Park.

The outsourcing of global drug development is risky. China's drug industry, long dominated by production of herbal and traditional medicines and generic drugs, is in the early stages of transitioning to a Western-style pharmaceutical system.

Eager to boost the credibility of its fledgling drug industry, the Chinese government has launched a major overhaul of the country's State Food and Drug Administration.

This week, the Chinese government sentenced the former head of the administration to death for reportedly taking bribes from companies trying to get approval for their drugs. During his tenure, dozens of Chinese died after ingesting fake or dangerous medicine.

U.S. executives said they were proceeding with care to ensure that their employees and subcontractors were working to U.S. standards and all research results would meet government approval in the U.S. and China. California is leading the trans-Pacific migration, thanks to its proximity to Asia and its large pool of expatriate Chinese scientists.

BioDuro Inc., a San Diego company providing contract research services to drug firms, recently opened a 40,000-square-foot lab in Beijing. Immusol Inc., a San Diego biotech firm developing anti-cancer drugs, is outsourcing chemistry work to firms in Beijing and Shanghai.

Much like how the U.S. software industry was forced to remake itself after the technology bust early this decade, the biotech industry is undergoing a painful readjustment as early-stage research moves to lower-cost countries. Ascenta's chief financial officer, Craig Kussman, came from Discovery Partners International Inc., a San Diego firm that closed up shop after it lost several large research contracts to companies in Asia.

A subsidiary in China wasn't in the business plan when Ascenta jumped into the crowded cancer field in 2003 with a compound derived from gossypol, a substance contained in cottonseed oil. Three decades earlier, Chinese health officials had traced an outbreak of male sterility in several villages to gossypol. It turned out that the villagers had been using unprocessed cottonseed oil for cooking.

World health experts discarded plans to use gossypol as a contraceptive because it was too effective; 99% of the men became sterile. But Yang and Wang picked up the trail, convinced that the protein inhibitors that killed the sperm might also trigger apoptosis, or cell death, in cancer cells. Their early research was promising.

But their timing was bad. Venture capitalists had gone into deep retreat, stung by the bursting of the technology bubble. With several promising drug candidates in the pipeline and limited funds, Ascenta's executives decided they had to figure out a way to buy more research for their dollars.

They found their answer in China, where the government had set its sights on developing a world-class biotechnology sector and was offering foreign firms cheap land, tax breaks, a huge pool of low-cost scientific talent and cheap raw materials. The savings were significant: A chemist with a doctorate earning \$20,000 to \$30,000 in China would be paid three to four times as much in the United States.

Ascenta Chief Executive Mel Sorenson said his company couldn't "manage the potential risks" of shipping a piece of its drug pipeline to China without Yang's expertise. "He is pivotal to our operation," the noted cancer specialist said.

Protection of intellectual property remains one of Ascenta's biggest worries. Although China has signed on to global intellectual property rules, the country is still the world's leading producer of pirated goods, including fake Viagra and Tamiflu.

Yang, who commutes regularly to China from his home in Ann Arbor, Mich., believes he can overcome that hurdle. He set up Ascenta's operation in China as a wholly owned subsidiary, which gives the parent company legal control over any discoveries made in China.

Most of Ascenta's discovery work is being done in Michigan and the promising substances are sent to Shanghai for further refinement and testing. Two compounds are in preclinical trials. The company's lead candidate, AT-101, is being studied in clinical trials in the U.S. for treatment of leukemia, lymphoma, lung cancer and prostate cancer.

Xiaolan Ling, a scientist at the prestigious Shanghai Institute of Organic Chemistry, said she joined Ascenta because she wanted to learn how to move a scientific discovery from the laboratory to the marketplace.

"This company is going to be a pioneer in China," she said.

To promote a sense of camaraderie and lessen the chances of losing talented employees like Ling, Yang has distributed stock options to his China staff.

As early movers, Ascenta's executives know their work will receive extra scrutiny from the U.S. and Chinese officials who oversee drug testing and sales in their respective countries.

Employees and contractors are required to follow internationally accepted standards for laboratory safety, sanitation and record-keeping.

"Sometimes people think there is a so-called Chinese standard," Yang said. "There's no way. There's only one standard. It's like the Olympics."

One area where Ascenta expects to reap savings of as much as 80% is in animal testing, an area where costs have skyrocketed in the United States because of limited supply, increased security costs and stringent regulations.

A company might need to conduct tests on thousands of animals to determine a compound's safety and efficacy. China has no strong animal-rights movement, a large supply of cheap animals and technicians willing to work for less than \$300 a month. A rhesus monkey, which costs \$5,000 to \$8,000 in the United States, can be bought here for \$500.

San Francisco-based Bridge Pharmaceuticals Inc. and Crown Bioscience Inc. of Palo Alto have set up modern animal-testing facilities in Beijing and are seeking international accreditation.

Yang and Jay Stoudemire, Ascenta's vice president of preclinical development, said they were proceeding with caution, having seen the dark side of this industry. They visited one monkey-breeding business in western China where the animals were crowded into a dirty, concrete facility.

"It reminded me of an apocalyptic chicken farm," said Stoudemire, who won't be acquiring animals from that business.

One of Yang's most crucial duties is cultivating relations with officials from China's State Food and Drug Administration, which is responsible for all applications to conduct drug trials or sales.

Western pharmaceutical executives say the administration is struggling to bring its operation to international standards and lacks the resources and the technical expertise to handle its expanding duties, including reviewing complex, Western-style new-drug applications. After Chinese officials launched a major corruption investigation of the administration this year, work at the agency slowed to a crawl.

Yang thinks it is too soon to conduct early-stage trials with humans in China because of the lack of experienced medical personnel and problems in data collection. But with deep-pocketed competitors such as Abbott Laboratories, Roche Group and Genentech Inc. chasing similar cancer treatments, he is keeping open the possibility that his firm might seek approval for human testing in China as early as next year.

"They are getting better," he said of the Chinese. "They are moving very, very fast."