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## Asia Spotlight: Meet China's New Innovators - Hua Medicine Looks To Take Flight With U.S. Venture Backing

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*On the second Monday of each month, “The Pink Sheet” provides exclusive news and commentary on the Asia biopharma market from the editors of its affiliated online publication, PharmAsia News. Register at [http://pharmasianews.elsevierbi.com/PAN\\_Trial\\_LP.html](http://pharmasianews.elsevierbi.com/PAN_Trial_LP.html) for a free trial.*

When multinational pharmaceutical companies began to establish R&D facilities in China a decade ago, they counted on Chinese returnees, or “sea turtles,” to head the new centers and help them get the lay of the land. Now, MNCs may soon be partnering - or competing - with these same sea turtles who have switched gears to become China's newest entrepreneurs.

What drives these pioneers to go out on their own? Many said the foundation has been laid for a rich ecosystem in China that is finally ready to support innovation. These pioneers also helped to build that ecosystem from the ground up and are anxious to move more quickly and nimbly than multinational companies can maneuver.

Many China experts anticipate that a wave of senior scientists who have worked for MNCs in China will soon look to leave and establish their own start-up companies. If successful, these start-ups could be a new, much needed source of innovation for Big Pharma, and in some cases may even take compounds forward that have been shelved by Big Pharma due to resource constraints.

Moreover, as local Chinese companies, these start-ups, in theory, can more easily cut through bureaucratic layers of red tape and also benefit from the massive amount of funding available from China's government to support innovation (*“Creative Funding Options For China; Investors Battle Perception of Home Court Advantage,” PharmAsia News, June 24, 2011*).

### Parks First Layer Of Ecosystem

China's science and technology parks, such as the Zhangjiang Hi-Tech Park in Shanghai, represent the first layer of China's ecosystem and the “business card to innovation in China,” said Li Chen, founder and CEO of Hua Medicine and former

chief scientific officer for Roche AG's R&D Center China. Roche was the first MNC to enter Zhangjiang, China's most prestigious park, in 1994 (*“Roche China R&D Center Chief Scientific Officer Li Chen On Being a Pioneer in China: An Interview With PharmAsia News,” PharmAsia News, Aug. 26, 2009*).

China's biotech parks offer government support and favorable policies, including government guidance. The goal is to foster a healthy balance between global and local R&D talent and provide a link to innovation by providing first-class infrastructure, William Keller, vice general manager of Zhangjiang park, told attendees of the BIO 2011 International Convention in Washington June 28. Keller, who ran Roche's China operations for 10 years, said the park represents the biggest talent pool for life sciences in all of China.

China's National Development and Reform Commission has designated Shanghai, Beijing, Guangzhou and Changsha as the country's four national pharmaceutical industrial bases. Each has a park with its own advantages and characteristics. Other well-known parks exist throughout the country, like BioBay in Suzhou.

And newer parks such as China Medical City, which is supported by the national government, are evolving into major players as the country's pharma industry continues its impressive growth (*“With Government Support, China Medical City Looks To Separate Itself From The Pack,” PharmAsia News, Aug. 3, 2011*).

In the last decade, innovation has come from all angles in China - from contract research organizations to MNC R&D centers, and now interest is building from the venture capital and investment community, said Samantha Du, CEO of Hutchison MediPharma, China's first homegrown biotech. One of the leading lights in the burgeoning China R&D space, Du, a former Pfizer Inc. executive, was among the first wave of returnees, establishing Hutchison MediPharma, the first biotech in Zhangjiang Hi-Tech Park, in 2002 (*“Hutchison MediPharma Founder And CEO Samantha Du On China's Drug R&D Ecosystem: An Interview With PharmAsia News,” PharmAsia News, Jan. 19, 2011*).

Du also highlights regulatory improvements as a key driver of innovation, noting that China's State FDA has evolved over the years, which has provided both local companies and MNCs with more confidence in China's ability to innovate.

Discovered in China, Hutchison's lead product HMP-044 is entering global Phase III trials, and could be the first oral botanical drug approved by U.S. FDA. Phase II trials were conducted in 223 patients in 50 centers in the U.S. and Europe.

Hutchison also was the first company to qualify for China's new green channel for fast-track approval; it currently has four products in this channel. The company has roughly 230 scientists, mostly led by sea turtles and top local talent (*"Hutchison MediPharma's Solid Tumor Drug First Oncology Project To Enter SFDA Fast-track Approval," PharmAsia News, June 26, 2009*).

### Returnees Taming China's Wild West

"C-level sea turtles have tamed China's Wild West and have led the industry and helped shape China's pharma industry from the ground up," Du told BIO 2011 attendees in June. Government funding over the last few years has helped build up those resources, and is helping China move up the value chain from "made in China" to "innovate from China," Du said.

The first wave of innovation began with sea turtles like Ge Li, who founded China's leading CRO, WuXi PharmaTech. The success of WuXi spurred others to enter the market, and China's CRO industry took off as Big Pharma looked to cut costs via outsourcing of preclinical research.

CROs have served as the foundation for innovation and technology in China, Hua Medicine's Chen said in an interview. Then a second wave occurred, with MNCs setting up R&D centers that brought international standards and helped to train leaders of the next generation.

More recently, a second wave of MNC R&D centers is emerging to focus on Asia-specific diseases, such as Eli Lilly & Co.'s new diabetes center in Shanghai (*"Lilly Shifts Gears In China With New Shanghai-based R&D Center," PharmAsia News, Nov. 3, 2010*).

As part of the first wave himself, Chen helped build up China's pharmaceutical industry, which continues to evolve - the landscape has changed dramatically, he says.

"A company like Hua can benefit a lot from that established capability," Chen said.

### China's Biotech's Next In Evolution Chain

"For the whole ecosystem to continue to grow, there is a need for biotech companies that can generate final products

to fit into major pharma R&D pipelines or continue to support local Chinese pharma companies to fill medical needs," Chen said.

The next step is to develop local biotech companies that emerge from academic universities to complete the cycle from discovery all the way through to commercialization of novel products.

"This is where I see a company like Hua can really contribute and take the lead to move this new wave forward," Chen said.

This third wave will involve identifying new drug targets and bringing them through to trials, or taking a compound from the U.S. or Europe and bringing it through clinical trials in China.

For Hua, the idea is not to build everything in house. Instead, the company intends to use CROs like WuXi and HD Biosciences for discovery technology and animal models, and Zhangjiang Hi-Tech Park and the Chinese Academy of Sciences for laboratories.

"You need to find the right people able to work with [local partners] and then the most critical thing is finding the best assets to invest in," Chen said.

Chen himself could also be seen as an asset. He has attracted \$50 million from American VCs, including Arch Venture Partners, Venrock and Fidelity Ventures. WuXi's Li has also invested in Hua Medicine (*"At PharmAsia Summit, VCs Discuss Financing Innovation in Asia," PharmAsia News, Oct. 28, 2010*).

"China is a great opportunity and many of those VCs, like Arch, never invested in China but they are the leaders in every run-off technology or historical moment," Chen said.

"When we met, [Arch Managing Director] Bob Nelson played a major role in this whole thing and he said, 'Li, I think you can do more in the biotech world,' and that's how we got started."

"They put a significant amount in the first round - \$30-50 million to hire the best people and find the best assets and do a first-in-class biotech company, not just a regular start-up."

After looking at hundreds of compounds, Chen is in discussions with several partners to license preclinical and clinical assets, and has nailed down four undisclosed programs he is interested in developing. Chen also noted that he is in discussions with major pharma, such as Merck & Co., Pfizer and Roche.

Hua's management team is relatively small with five or six people who have expertise in business development, medicine, biology, translational science, chemistry and drug safety.

Co-founder and Chief Strategy and Business Officer John Choi, a managing director at Pytho Partners PanAsia and former principal at Venrock, holds a Ph. D. from Harvard and

an M.D. from Cornell. At Venrock, Choi focused on several portfolio companies, including RNAi play Sirna Therapeutics, which was acquired by Merck, and Coley Pharmaceuticals, which Pfizer acquired in an effort to boost its capabilities in biologics and vaccines ("*Pfizer Strengthens Therapeutic Vaccine Position With Coley Purchase*," "*The Pink Sheet*" DAILY, Nov. 16, 2007).

"He really has the knowledge base and the understanding, which makes it easier when we interact with our U.S. partners and licensing partners or interact with investors," Chen said. "It makes a whole lot of difference when you have a team who themselves are leaders in the area."

### Local Government Support

Chen has met with Shanghai government officials who have offered to help with office space, land and research facilities with good terms as a gesture of support.

"You want to set up an example of using taxpayer money diligently and then use that money as your own to deliver on a product and have a good return on investment," he said. "In time, and depending on the needs of our asset development and our team, we will approach the proper financial partnership."

Chen noted that developing innovative drugs for China represents a new step in China's evolution. For example, diabetes in China appears differently than in the West, with people developing the disease who are not obese, and so there is a need for drug development based on different ethnicity.

"We're working with medical clinics and hospitals and that's what the government wants to see, so that the new medicine we develop will be different when it reaches patients in China, instead of following on the existing trend of one size fits all."

Hua will focus on developing drugs for cancer, diabetes and CNS disorders.

Hua's five-year plan? "We would like to see a drug approved on the China market and have one or two molecules entering Phase III," Chen said. "After [proof of concept] in China, we will continue to develop new medicine in China and partner with people in the U.S. and Europe for global development. Also, in the area where we are engaged in early discovery, we will be working closely with hospital experts and disease experts in China to come up with better or new drugs not available for that disease."

The initial financing will provide the company with a solid footing for the next three to four years, but Chen believes Hua's investors are in it for the long haul.

"We have a group of investors that really understand the value. They said not to worry about getting to the IPO, but [focus on] the healthy growth of Hua as a company."

And he pointed to the growing trend of U.S.- and EU-based small cap and medium-cap biotechs going to China, all of which could be future partners for Hua Medicine.

