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BIO 2011 International Convention

BIO Calls for Tax Changes, New Approval Path, Independent FDA

By Mari Serebrov
Washington Editor

WASHINGTON – Recognizing that regulatory science isn't keeping up with innovation in the U.S., the Biotechnology Industry Organization (BIO) donned its thinking cap to come up with some practical solutions.

The result is a package of policy proposals to reform the investment and regulatory environment for biotech innovation, including an independent FDA with the resources and authority to do its job.

"The legal and regulatory structures in place remain woefully insufficient to incentivize the magnitude of investment necessary in the biotechnology sector to translate the scientific potential that resides in the thousands of small, medium and large American biotech companies

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Biotech Innovation in China: 'We Can Do it From A to Z'

By Tom Wall
Staff Writer

Jinzi Wu, CEO of biotech start-up Ascletis Inc., has flown so often between the company's China headquarters in Hangzhou and U.S. facility in Research Triangle Park, N.C., that he said he's not a "sea turtle" – the phrase for returning Chinese scientists – but rather a "sea gull."

Li Chen, the president and CEO of start-up Hua Medicine, expects his company to lead biotech innovation in China. "We can do the whole nine yards," Chen said. "We can do it from A to Z."

Both men, with U.S. university educations and big pharma experience, are among the trailblazers in the evolution of biotech industry in China from services to discovery and innovation.

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They joined Steve Yang, Shanghai-based head of R&D in Asia for AstraZeneca plc, and venture capitalist James Huang, of Kleiner Perkins Caufield & Byers's Shanghai office, as part of a Wednesday panel at the BIO International Convention, "From 'Made in China' to 'Discovered in China' – Challenges and Opportunities." The session, one of many during the convention focusing on China's evolving biotech industry, was moderated by Wenseng "Wendy" Pan, an attorney for Morgan, Lewis, Bockius in Philadelphia, whose practice includes advising multinational pharmaceutical companies and biotech start-ups.

Although the panelists' work gave them views of the emergence of biotech innovation from different perspectives, their messages were similar: Despite financial and regulatory challenges, it is only a matter of time – perhaps as little as a decade – before China becomes a world leader in innovation.

Wu's Ascletis stands as an example of how quickly it might be possible for biotech innovation to gain momentum in China.

Wu, who received his PhD in cancer biology from University of Arizona and gained experience with Ambrilia Biopharma Inc., Immunex Corp., Amgen Inc., Novartis AG and Sanofi-Aventis SA, left his job as vice president of global HIV drug discovery for GlaxoSmithKline plc in February to start the company. "I told myself it would be more fun than GSK," he said. "And there is a sense of urgency in China." The new company would focus on oncology (liver, lung and stomach cancers), and infectious diseases (drug-resistant tuberculosis) for which there are major unmet medical needs in China, confident that good things could happen. "Drug discovery takes years, but in China everything is high speed," he said.

By April, the company announced an attention-getting $100 million committed Series A funding, with the first $50 million tranche expected to support it for about five years. Hangzhou Binjiang Investment Holding Co. Ltd., a holding company of Chinese real estate billionaire and Wu's long-time friend Jinxing Qi, led the round, with other investments from entrepreneurs in China, the U.S. and other countries, and from Wu. (See *BioWorld Today*, April 7, 2011.)

Ascletis has a dual operation strategy. First, generate near-term revenue by in-licensing Phase IIb assets and later programs for the Chinese market. Second, discover and develop oncology and infectious disease drugs, advance the programs through clinical proof of concept, and then find big pharma partners for late-stage development and commercialization.

Despite his company's encouraging start, Wu said that financing for innovative biotech is an ongoing challenge.

"It has been hard to get money for biotechnology," he said. "There have been a lot of other opportunities, and investors understand the risks in biotechnology. In order to attract money in China, you have to show investors that you are going to build a business with quality, because without quality it will not succeed. You also have to set the expectations for investors and be honest, truthful and 100 percent transparent. Our focus is to have quality and trust."

Quality also figures into another challenge Wu sees for innovative biotech in China: regulatory issues such as China's standards for clinical trials.

"There is a gap between the standards of China's State Food and Drug Administration and global standards like those in the U.S. and EU," he said. "If you have suboptimal quality, it affects your global strategy. China needs the same standards as the U.S. and EU countries. It cannot compromise. The challenges are the reality that clinical trials need to mature and the mindset of some people that we can cut corners in clinical trials."

Nevertheless, Wu is optimistic about the potential for innovation. "You can wait until everything is perfect, but you will lose opportunities," he said. "If you get in now, it is a calculated risk but you will grab a great opportunity."

Like Wu, Chen attended a U.S. university – a PhD in chemistry from Iowa State University – and worked for big pharma – returning to China in 2004 as chief scientific officer and head of drug discovery research at Roche AG's R&D center in Shanghai.

He started Hua – which has China headquarters in the Zhangjiang High Tech Park in Shanghai and a U.S. office in Princeton, N.J. – to discover, develop and commercialize new drugs targeting specific Chinese needs. "I always wanted to make a drug, to create a medicine for my fellow people," he said.

He said that he has seen the capability to do that since 2004, in part because multinationals who located R&D facilities in China brought standards and leadership; in part because contract research organizations brought the technology needed to do drug discovery; and in part because of a growing pool of talent including returning Chinese scientists who will become the leaders of biotech start-ups.

Li said he has raised about $50 million from investors since starting the company last year. "Company-based drug discovery is a new concept," he said. "Academic institutions did all of the drug discovery until four or five years ago and the government sponsored all of the research. Today it is being driven by entrepreneurs, not the government. But it is hard to get money because they don't know if what you are doing is a good project. But they are learning."

Li said he has people and financing in place and is discussing multiple deals with multinationals and Chinese academic institutions. Hua is positioned, he said, to "move to the next step and then lead the innovation. The focus of the company is to produce a product and then market the drug in China and the rest of the world."

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Other News To Note

• **Inovio Pharmaceuticals Inc.**, of Blue Bell, Pa., said its therapeutic DNA vaccine INO-5150 for prostate cancer-generated T-cell immune responses in monkeys. The company plans to start a Phase I trial in 2012.

• **Ondine Biomedical Inc.**, of Vancouver, British Columbia, agreed to be acquired for C$3.19 million (US$3.29 million) by a private entity whose sole shareholder is Ondine CEO Carolyn Cross. The acquisition price represents a premium of approximately 65 percent over the closing price of the stock on Tuesday. Ondine's board unanimously approved the agreement.

• **Regeneron Pharmaceuticals Inc.**, of Tarrytown, N.Y., and partner **Bayer AG**, of Berlin, submitted an application to the Ministry of Health, Labor and Welfare in Japan for approval of Eylea (aflibercept injection) in wet age-related macular degeneration. The product is under FDA review as well and recently received endorsement from an FDA advisory committee. (See *BioWorld Today*, June 20, 2011.)

• **Strativa Pharmaceuticals**, of Woodcliff Lake, N.J., a division of Par Pharmaceutical Cos. Inc., reduced its work force by 100 positions. The restructuring was part of a strategic assessment aimed at making the company profitable.

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In an earlier session on China – Tuesday's "Can A Western Business Succeed in China?" – Curis Inc. CEO Daniel Passeri said that the Lexington, Mass.-based cancer company has continued its innovation work stateside, but has since 2005 worked with medicinal chemistry partners in China.

Passeri said the arrangement saved the company money, compared to sourcing the work in the U.S. or Europe, but also enhanced productivity. With biology based in Massachusetts and chemistry in Shanghai and the 12-hour time difference between the locations, work is ongoing on a program somewhere virtually around the clock, he said.

"It augments and complements what we're doing," he said. "We continue to look at ways of expanding competencies in China. It has been much more productive and prolific than anticipated. We are starting to entertain a risk-sharing relationship with some biopharmas in China. We also are entertaining doing preclinical development work there." ■