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A Snapshot of Updates In The APAC Region

by David Wild

US-China tensions, the increasing importance of Singapore as a doorway to the Asia-Pacific region, growing AI innovation in South Korea and a changing clinical trials landscape in Japan are just some of the recent developments in APAC.

Asia-Pacific countries are pulsing with biotech innovation, but growing geopolitical tensions between the US and China are dwarfing news of opportunities and developments in the region. Even with growing economic belligerence between China and the US, biopharma companies and investors ignore the region at their peril.

To be sure, the friction between the US and China has impacted biopharma.

As Art Pappas, managing partner at US venture capital firm Pappas Capital, said during a panel discussion at January 2024's Biotech Showcase conference, all of his firm's investments in China now require US State Department approval. That slows down the process and can have material impacts.

"It's a difficult situation, because you've got an ethical line around some of the technologies that the Chinese and the Americans don't want you to access," he reflected.

Tensions between the two countries have culminated in the BIOSECURE Act. If passed by the US government, it would ban US life sciences companies from contracting with biotech companies that have ties to the Chinese government. Chinese genomics companies BGI Group, [MGI PHARMA](#), Shanghai-based [WuXi AppTec Inc.](#), and their affiliates, are named in the Act.

The proposed bill is having a chilling effect on US deals in the region, and the Biotechnology Innovation Organization recently threw its support behind the Act. WuXi was also removed from its membership. (Also see "[China Biotech Hopes Innovation Wins The Day As Legislative Attacks In US Congress Increase](#)" - Pink Sheet, 14 Mar, 2024.)

However, other companies are moving ahead with deals as China's thriving biotech sector is a source of new therapeutics that big pharma needs to fill its diminishing pipelines. China has been practically doling out antibody-drug conjugates to companies like [Roche Holding AG](#), which signed a \$1.05bn ADC licensing deal with MediLink Therapeutics Ltd., earlier this year. (Also see "[Roche Signs Up Medilink As China Biotech ADC Deal Spree Continues](#)" - Scrip, 4 Jan, 2024.)

More recently, [ArriVent Biopharma, Inc.](#) signed an \$800m deal with Shanghai Allist Pharmaceuticals Co., for furmonertinib, a small molecule oncology drug already approved in China for non-small cell lung cancer.

While there have been licensing deals with Chinese companies, the appetite for mergers and acquisitions has dampened. According to Evaluate, there has been only one Chinese M&A this year, [AstraZeneca PLC](#)'s acquisition of [Gracell Biotechnologies Inc.](#) for \$1.2bn, which, according to Pappas, was largely a product of Chinese disincentives to move multinational companies' earnings outside of China. In contrast, there were 37 M&A biopharma deals in China 2015.

Singapore An Important Access Route

Seeing the impacts of US government intervention, some Chinese companies are opening offices in neighbouring countries, like Singapore. According to Guy Heathers, chief business officer of Singapore-based Albatroz Therapeutics, and a veteran of Singapore's life sciences sector, roughly 200 Chinese companies registered offices in the city-state in 2023.

"That's obviously due to the unfavorable political climate," Heathers said during the Biotech Showcase panel, noting that it is unclear whether these moves are purely legalistic or whether the companies plan on moving facilities to Singapore.

The flight of Chinese companies to the city-state means that creating connections with Singapore is ever more vital for biopharma companies. Indeed, Singapore is one of the APAC geographies that Pappas Capital's \$200m Asia Innovation Ventures Fund is focused on.

"Singapore has spent a lot of money to... make it a very credible and non-corrupt place and a springboard to other countries in the region," Pappas noted.

"The novel drugs and developments are coming out of Korea, Japan and China." - Art Pappas, Pappas Capital.

While he has seen an “impressive” number of patents originating in Singapore, the caveat is that many are not for “major impact items.”

“The novel drugs and developments are coming out of Korea, Japan and China,” said Pappas. “Getting your hands around those places, from a globalization basis, is going to make a difference in building an international company.”

Heathers echoed that sentiment, stating that while Singapore boasts a strong innovation ecosystem, there is still work to do in translating research into intellectual property and moving it towards commercialization.

“There have been one or two drugs that reached late-stage development, and some that are even marketed, but a lot of the development is done outside of Singapore,” Heathers noted.

Japan Eases Clinical Trial Requirements

Elsewhere in APAC, changes in the clinical trials landscape in Japan have occurred over the last year. This has happened in the context of a continued push towards global clinical trial regulation harmonization and integration.

Japanese [Astellas Pharma, Inc.](#) has been conducting multi-regional clinical trials to reduce its time-to-market, said Yoshi Shitaka, the company’s chief scientific officer. Indeed, an MRCT for its first-in-class CLDN18.2-targeting antibody, zolbetuximab, helped the company file an unprecedented 13 regulatory submissions within a three-month period in China, the US, Europe and Japan, the latter of which recently granted the first approval to the drug. (Also see "[Japan Grants Global-First Approval To Zolbetuximab, 15 Other New Drugs](#)" - Pink Sheet, 29 Mar, 2024.)

Singapore: A Country Punching Above Its Weight

By [David Wild](#)

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With strong government support over the past two decades, the Singaporean life sciences industry has matured. Initially known as a manufacturing hub, Singapore’s innovation ecosystem is now thriving, but the challenge is to cultivate commercialization power.

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"The globalization of drug development has been a great benefit for Astellas." - Yoshi Shitaka, CSO, Astellas Pharma

“Previous products took more time to bring to regulators and there was more of a lag among countries,” said Shitaka. “The globalization of drug development has been a great benefit for Astellas.”

Notably, the Japanese Ministry of Health, Labour and Welfare recently relaxed requirements for drug companies to conduct local Phase I studies before enrolling Japanese participants in later-stage MRCTs. (Also see "[Japan Planning To Expand Phase I Waivers](#)" - Pink Sheet, 5 Oct, 2023.)

“That’s a very good change and allows pharma to participate in MRCTs in a timely manner in Japan,” said Shitaka.

Korea Moves On AI

Korea has been strengthening its reputation as a biotech innovation hub, with the country’s government recently announcing significant investments to cultivate local biotech clusters. One focus is on artificial intelligence-led drug discovery and development. In recent remarks, South Korean president Suk Yeol Yoon indicated that while it is unlikely for South Korea to compete on the same level as western biotech hubs, the country has an opportunity to excel in cutting-edge AI and digital technologies. (Also see "[Window Of Opportunity: Korea Unveils Cutting-Edge Bio Initiative](#)" - Scrip, 31 Mar, 2024.)

Government investments in an “AI and bioscience talent school” might be one reason big pharmas like [Johnson & Johnson](#) and [Merck KGaA](#) are also deepening their presence in the country.

Cultural Considerations

As varied as APAC countries are – and as mixed as the risks and opportunities in the market are – doing business with countries in the region is inevitable for many biopharmas. With that in mind, non-APAC companies should acquaint themselves with cultural norms, advised Martina Molsbergen, CEO at Philadelphia-based C14 Consulting Group, LLC, which provides business development help to biotech, venture capital and pharmaceutical companies.

For example, global companies need to be aware that Chinese companies in particular have been known to make unexpected changes in terms of an agreement, be non-compliant with those terms, or, in some cases, include terms that do not reflect the reality of the situation.

“You might license something from a company in China and sign an agreement for a list of things and then find that some of those things are not ready for prime time,” she said at Biotech Showcase. “So, diligence needs to happen, but even with diligence sometimes things can fall through the cracks.”

Conducting business with Japanese companies tends to be smoother, she noted, since there is

greater transparency, information-sharing and a commitment “to making the deal work.”

With the growing importance of APAC as a source of innovation, many companies will be doing business in the region. For those interested in creating a presence in the APAC region, Pappas recommends moving in a “stepwise fashion.”

“When you’re entering a market, start with an affiliate, then go to a possible joint venture, then go to a subsidiary,” he advised. “They’re huge markets with terrific technology.”

The Importance Of Relationships

In the APAC region, relationships can be more important than written contracts, Pappas noted. Negotiating with that understanding was key to creating a successful partnership, he said.

“If you as a foreigner are going in and trying to manage the situation as an American or a Brit or Australian, it’s not going to be the same, and you have to be sensitive to that, and sometimes a mistake can be costly,” he said.

Heathers agreed with that advice, adding, “there’s obviously a lot of opportunity in the region but also some challenges, and to be aware of those challenges is a good first-step.”

“Working with someone who’s done business in these countries is a huge benefit if you want to try and prevent potential pitfalls and mistakes,” he advised.