

What's behind the rise of China based biotech innovation and what's next?



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Questions & Answers

Questions and Answers with De Facto [DF] Team and Claudia Lin [CL] to try and predict short, medium and longer term implications

Biobeat question: What is your overview on the present outlook for the biotech industry in China and how its innovating?

CL: *"In the past decade, China biotech industry has not only secured its status as the R&D hub for the world's pharmaceutical industry, but it has now emerged as a highly competitive innovative biotech product development center for the world. This is reflected by the rapid increase of out-licensing deals from China-based biotech to the rest of the world in the last 3-years - and significantly this is most often to the established global big pharma players in the West (MNC), but also to some developing market players who are using these targets to get ahead of similar competitors in the rapidly changing global pharma supply chain. But what is undoubted now is the quality of these assets from China, these are world-class targets that encompass all therapeutic modalities from traditional biologics to the most-advanced cell and gene therapy varieties."*

Biobeat question: There was talk until very recently [maybe just 18 months back] that China-based biotechs are struggling - as were the CDMOs there [WuXi aside] due to domestic market returns remaining poor and innovation was largely 'me to'... so has the industry in China therefore shifted focus to attempt - well succeeded in fact - at becoming a global innovation hub. Meaning it can access the high margin/profit in the US market. How has this shift been achieved?

CL: *"Indeed, I was on the ground in China from 2015-2024 and witnessed first-hand the rapid rise of the Chinese biotech industry. This came from central government's long term strategic focus - with cash poured into the industry alongside supportive policies including infrastructure investment, talent investment and rebates."*

WuXi Aptec is a really good example of industry being positioned for the future as well as present. And by that I mean having the foresight to not just invest for what the industry needs today, but also for how Chinese drug regulation and wider market would evolve.

These two factors converged into a perfect storm so that WuXi was ready to provide global solutions and it really was in "the right place at the right time". However, WuXi did not become a global name overnight, it went through many years of maturation, especially in areas that other Chinese companies all struggle with today, namely, the Quality and Compliance of its manufacturing to meet Western standards. WuXi's success in the full product development lifecycle has further propelled its success as a comprehensive service company at the global level. By contrast, many other Chinese CDMOs that either were in the same business before or after WuXi, especially in the biologics business, are still unable to manufacture biologic products that can be approved in the US or EU. Therefore, I would argue that WuXi is not representative of the level of strength of the entire Chinese biotech industry - it's a unique and special case.

Chinese biotech has, on the whole, not broken the glass ceiling of being a fully integrated biologics product development or service companies, but rather, has refocused itself to be the innovative hub for biotech R&D and early stage biotech product assets generation. The part they are yet to fully master is how to progress and complete late-stage development and achieve not only product launches world-wide but also commercial successes. This is a high bar even for many of the Western biotech companies and the Chinese are not there yet. This is also why they now have chosen to partner with western companies to go to markets outside of China."

Biobeat question: In 2024, out-licensing agreements from China based biotech soared to over \$50 billion, up from approximately \$5 billion in just 2020, accounting for about 30% of global licensing deal value. How do you see this taking landscape evolving in the next 18-months?

CL: *“China’s now rapidly maturing as a global R&D hub for biotech. How did they get here, well go back 15 years to when US based global pharma was cutting its R&D functions following 2008 financial crises. Many excellent Chinese born scientists working in the US decided to return to China, in search of better career opportunities. They were the first generation of entrepreneurs in Chinese biotech industry, and they were fortunate to be in their home country when Chinese government began to propose biotech as one of the national strategic focuses in the Chinese government’s “Twelfth 5 Yr Plan”, it enabled them to receive tremendous government support to start their business mostly in R&D. Additionally, there are many MNCs that had R&D centers in China and over the years they have also served to train local Chinese scientists to generate a world class biotech R&D talent pool in China. Therefore, the R&D expertise in China has had a long time to mature, including the level and quality of innovation to create from “Fast Follow-on”, to Bio-Better” and, in more recent years, “First-in-class” R&D assets.*

Chinese biotech has more quickly evolved from 2014 to now, through trial and error, and by sheer high volume of biotech companies trying to develop biologics products in a highly concentrated fashion. As more biosimilar and innovative biologics companies have developed the wider ecosystem beyond R&D and modalities way beyond insulins and other biosimilars, Chinese biotech industry as a whole has become also highly experienced, particularly as an early clinical stage exporter to the West.

My prediction is therefore that the progression of utilization of this strength is a natural and neutral outcome, and the level of out-licensing seen today is actually in line with the wider progression – so we will not see any decrease in the next 18 months of this volume of China based innovation.”

Biobeat question: Longer term, say five years hence, will China be seriously rivalling the USA as the world centre of bio innovation - what are you seeing in the pipeline there? Or do you think that China is already approaching this... or is the current output a temporary period of innovation and may fall back?

CL: *“I would say China is already approaching this status. In the past five years, innovation in Chinese biotech has gone from anti-PD-1 Mabs to all of the new therapeutic modalities, the most prominent being bi-specific Mabs and ADCs where they arguably now lead.”*

Biobeat question: Do you think WuXi’s global success as the key CDMO behind by far the most innovative medicine of the last decade [e.g. it's believed to be approaching 100 commercial FDA approved drugs now] and its subsequent switch toward developing increasing numbers of domestic drugs [i.e. since it was fearful of losing Western commercial work as BIOSECURE advanced]... has this helped China accelerate its innovation base, and even contributed to it... **or is the timing just coincidental** and this breakthrough moment has been coming for some time [i.e. since BIOSECURE came on to the agenda in late 2023 China appears to be accelerating innovation - and historically WuXi favoured US based clients]

CL: *“WuXi started as WuXi AppTec, which was a CDMO for small molecules. WuXi Biologics was established in China, following the initial success of WuXi AppTec in the US, and then in China, and was becoming a very successful business unit in China’s rise of biotech industry around 2014, and it supported the first FDA approval of a biologics product manufactured in China. However, not all Wuxi enterprises are successful, and some suffered from “too fast and too big to be good” business cycles; WuXi AppTec later established WuXi Advanced Therapies Unit [ATU], and overall, it was not viewed as a successful business with an eventual divesture of its*

US operations to an investment firm in 2024. WuXi now also has ADC and other nucleic acid based CDMOs, and the overall systems and operational models are mature and hence maintaining a great reputation world-wide.

Which is a longer way of saying, of the 100 FDA commercial approvals, the majority did not come from WuXi Biologics, and are for small molecules, so the gap in biologics product late stage development and commercial success from Chinese biotech still holds.

WuXi's success has very much accelerated the success of Chinese biotech industry in general, and BIOSECURE did not directly target the vast majority of the Chinese biotech companies."

Biobeat question: What challenges does China currently face? and is the geopolitical tension with the USA the only handbrake holding back its innovation base [whether tariff base / BIOSECURE / Taiwan etc etc]

CL: *"Actually, the main challenges of the Chinese biotech industry are to improve the quality of late-stage clinical development - this is due to significant gaps in designing clinical trials for innovative therapeutics that don't yet have many Western examples to follow. 2) GMP manufacturing and associated Quality management of Chinese biotech, WuXi aside, is yet to match the compliance standards of the advanced markets such as US, EU and Japan.*

The net result of this is that China based innovators don't yet have commercial success, in the West. While an overall low ROI in biotech investments was causing market depression for a period of circa four years, and was viewed as general set-back in confidence in pursuing late-stage commercial therapeutics by the Chinese companies themselves."

Biobeat question: Has government funding helped give China an advantage and, at a time when the US is cutting early funding, could the gap get larger?

CL: *"Chinese government support was fundamental to possibility of biotech industry, and I saw first-hand how much money was allocated to the biotech industry, similar to the electric vehicle industry etc.*

However, Chinese innovation is mostly 'translational innovation' or an expansion of the truly ground-breaking original innovation - the latter of which remains largely rooted from the US, Europe and Japan. Therefore, the US funding cuts to some basic research, is dangerous from strategic point of view as it carries the risk of stopping source of original innovation at its root which, in time, will affect the rest of the world."

Biobeat question: What advice would you give global pharma or global VC looking at the booming China market for opportunities?

CL: *"I would reiterate the need to understand systematic strengths and weaknesses and put maximum due diligence efforts into the potential weaknesses. And to understand that Chinese are very smart and eager and able to learn, so if the west wants to maintain competitive edge it must be very alert on how to protect its competitive edge. For example, this means when undertaking a due diligence process, don't just have experts who are only going to read a report from a Chinese company in English. But rather, engage in a detailed dialogue in Chinese with people on Chinese side - it obvious but language and cultural understanding are crucial to success here."*

Biobeat question: China is known to be heavily invested in AI - what do you predict that means for its role in global innovation over the next 5-years?

CL: *"China is so good at applying new technology - AI being one of them - however, they are not as invested in generating new models, but rather applying it to everything. So my view is I see China becoming a leader in AI application and as a tool to support discovery and development programs."*

Biobeat question: Looking one decade ahead what would you predict?

CL: *"The current trend will continue for the next 5 years. The big question of course is can Chinese biotech overcome their weakness in late-stage development and manufacturing and therefore begin to launch their home-born assets into the West directly. I think it may be able to do achieve that in five years' time."*

