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Accessing biopharma innovation in China

Rethinking strategies to play and win in China's rapidly growing and evolving biopharma ecosystem

Introduction

Over the past five years, China has shifted from being the supporting act in the global biopharma ecosystem to being center stage with respect to innovation and deal-making. Chinese government initiatives, such as "Made in China 2025" and the rapid expansion of infrastructure to support innovation, such as the Beijing BioPark, have fueled a shift to developing innovative first-in-class and fast-follow drugs. At the same time, China has seen regulatory reforms – including accelerated approvals[1], Research and Development (R&D) subsidies[2], and an increase in cross-border trial data sharing[3]. These initiatives have been a catalyst for growth in top-tier talent and research institutions[4]. These factors, coupled with lower costs and a large population with diverse disease profiles, have created opportunities for global players that substantially evolve the risk/benefit trade-off of engaging in China.

This changing paradigm can require global pharma to evaluate their positioning in and strategies to access innovation in China.

1. Understanding the market as a foundation for success

a. Regulatory Environment: China continues to make significant strides to establish an attractive environment for development, though regulatory risks and geopolitical uncertainties persist.

First, it is critical to understand the market and how China has evolved its regulatory framework to attract global investment. By joining international regulatory frameworks like International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) in 2017 and updating its pharmacopeia in 2025[5], China has demonstrated its commitment to global standards, fostering a more favorable environment for international stakeholders. At the same time, cross-ministry policies such as national anti-corruption campaigns in the pharmaceutical sector[6] led jointly by the National Health Commission (NHC), National Medical Products Administration (NMPA), and other ministries, have expanded inspection scope to curb corruption and protect businesses operating in the market. Data protection laws and guidelines have similarly been bolstered, including through the establishment of four mechanisms for cross-border transfers of personal information, namely: (1) a security assessment; (2) the filing of the standard contract for cross-border transfer ("SC"); (3) a personal information protection certification; and (4) exempted scenarios. These measures, alongside clinical standards that are increasingly aligned with global norms, have helped to create a friendlier and more conducive environment for research and trials.

Despite these tailwinds, development in China is not risk-free. Global players should remain mindful that, even with advances in clinical and data standards, key hurdles persist in levels of IP protection, data acceptance outside of China, and genetic data and plasma collection. Ex-China data acceptance continues to be a major concern among these matters: western regulators have demonstrated a reluctance to accept China-only data, delaying go-to-market for China-developed assets. There are a handful of examples of FDA approvals due to lack of non-Chinese patient data[7].

Additionally, broader macroeconomic pressures and evolving geopolitical tensions add another layer of uncertainty and volatility that can influence both operations and capital allocation decisions. For example, IP transfer from Chinese academia or startups may be restricted by geopolitical or national interest considerations, creating barriers to cross-border collaboration..

While China's evolving regulatory and investment climate has become increasingly attractive for multinational participation, it remains a complex and unpredictable landscape.

b. Understanding the advancements and innovation driven by Chinese biotech

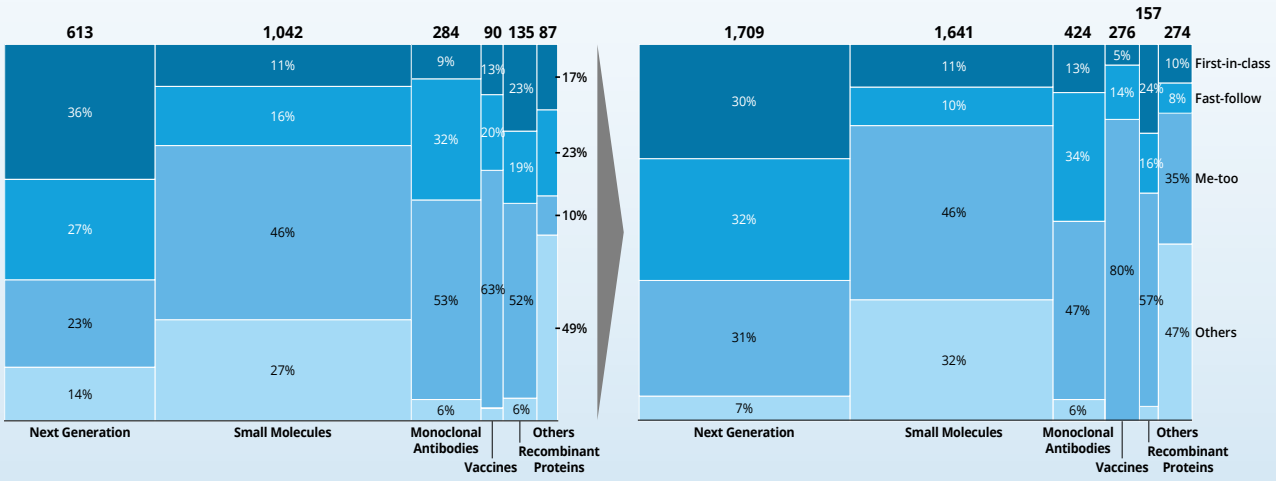
China's biopharma sector has grown into the world's second largest, with it accounting for approximately 30% of the global innovative drug pipeline.[8] This growth is underpinned by substantial government investment, regulatory reforms, and the integration of advanced technologies such as AI, cell and gene therapies, and radioligands. Additionally, Chinese cities like Shanghai[9] and Suzhou[10] have become innovation hubs, hosting thousands of life sciences companies and attracting both domestic and international capital.

China's growth in volume continues to be primarily driven by me-too and fast-follow products, which represent over 60% of pipeline products (Figure 1). However, research is weighted towards next-gen modalities, establishing China as a future leader in these new modalities. By clinical trial volume, China ranks number one globally for ADC biologics and number two for both Cell and Gene Therapies and Bispecific Antibodies / Polyclonal Antibodies.[11] There is also an upward trend in First-in-class launches from China companies, with the National Medical Products Administration (NMPA) approving 40 domestic first-in-class drugs in 2024.[12],[13]

China also continues to demonstrate diversity in therapeutic areas, with oncology (22% of 2024 registered clinical trials), metabolic (17%), and cardiovascular disease (13%) representing the top three development areas.

Based on current trends, China may not necessarily be the global leader for "first-in-class" treatments for now but instead a hotbed for more affordable "best-in-class" treatments.

Figure 1. Pipeline volume by molecule type

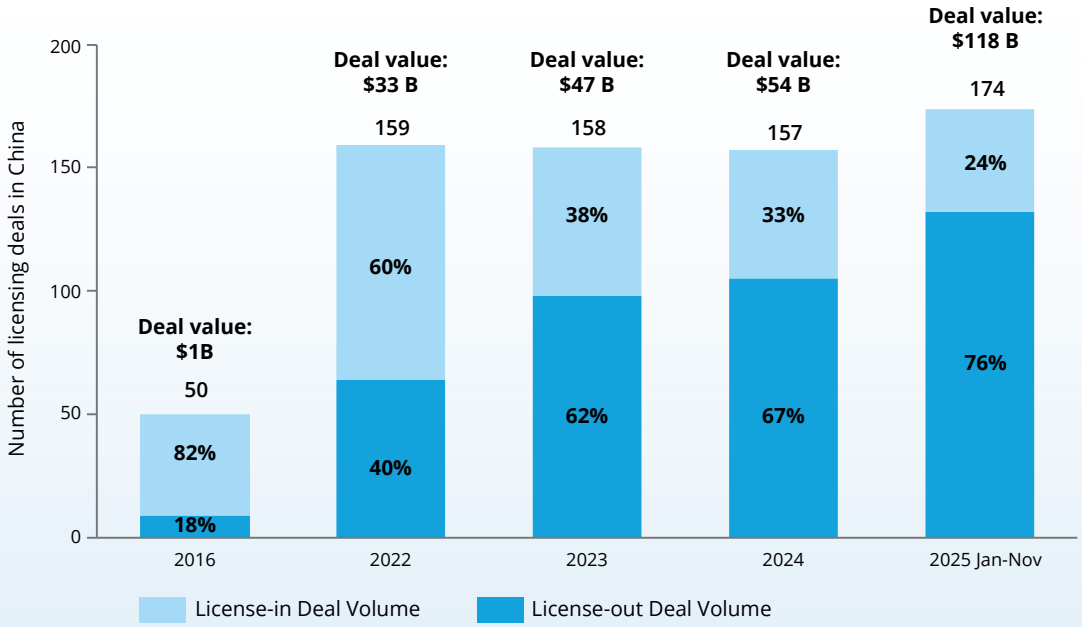


Note: [1] including drugs forming part of FDCs and those lacking sufficient information for categorization;[2] those not fitting into any existing categories.; drugs with novel targets or novel MoAs were defined as either first-in-class or fast-follower based on whether or not they have class-leading clinical development status worldwide; drugs with the same targets and similar MoAs as already-approved drug classes were considered me-too. Source: Nature, Deloitte Research

c. Understanding deal-making activity and common deal structures

Parallel to the growth in development has been a change to both the scale and nature of deal-making activity in China as companies looked to take part in the evolving ecosystem. The number of annual global drug licensing deals involving Chinese companies rose from 50 in 2016 to 174 in 2025, accompanied by a 100-fold increase in total deal value for Chinese biopharma assets (Figure 2). In 2025, total deal value for Chinese biopharma assets reached approximately $118 billion (Figure 2). Three quarters of these licensing deals now involve the out-licensing of China-originated assets (e.g., therapies discovered and initially developed domestically, but commercialized by global collaborators), particularly in high-value areas such as oncology, immunology, and cell therapies, indicating the growing international demand for China innovation.

Figure 2: China Growth in Licensing Activity (2015–2025)



Source: Deloitte analysis of Pharmacube data

A wide range of players, from institutional investors to established Biopharma companies, have continued to make deals in China; however, the deal approaches that global biopharma companies leverage has changed over time. Though the historic focus has been "China for China" in-licensing deals, Global biopharma companies are leveraging traditional out-licensing (typically of ex-China commercial rights) and M&A as well as innovative incubator and venture capital models to access innovation as part of "China for Global" strategies.

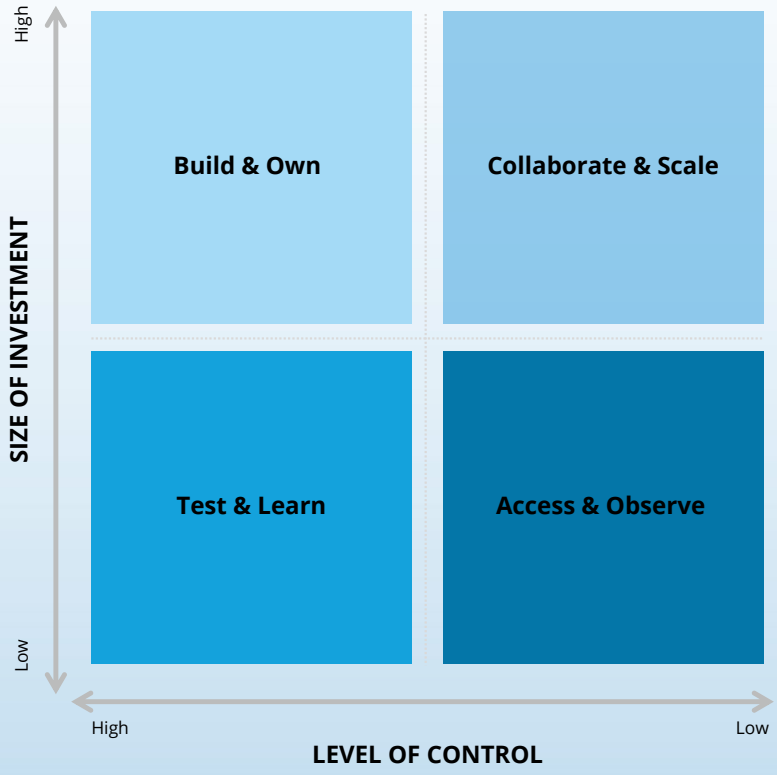
While there continues to be a robust pipeline for deal activity, the increase in participants, deal approaches and deal volume highlight increasing competition to access the quality opportunities, necessitating thoughtful strategy to prevent overvaluing assets and mitigate other risks.

2. Rethinking strategies to gain access to Chinese innovation

a. Successfully accessing innovation

As China cements its position as a global innovation hub, biopharma companies are rethinking how they participate in its ecosystem. The choice is increasingly not whether to participate, but how to do so in a way that balances control, speed, and risk. Four strategies are emerging, each with their own unique advantages, based on level of investment, risk appetite, and strategic ambition.

Figure 3: Strategies for accessing Chinese innovation



Source: Deloitte Global

High investment strategies:

- **Own and build:** Investing deeply into building a China footprint allows for long-term relationship building and favorability amongst local participants and regulators. Though this approach often requires a significant time horizon and long-term commitment, these participants typically see advantages in market access for commercialization and tap directly into the advantages of cost-effective R&D in China.
- **Collaborate and scale:** Leveraging local biopharma participants helps enable speed and comparative flexibility to react to changing market circumstances while accessing local know-how and channels via the established collaborator. However, loss of control is the trade-off for this flexibility. Having a trusted collaborator is essential for success.

Low investment strategies:

- **Access and observe:** Tapping into early-stage innovators allows for a smaller investment while maintaining access to the local innovation scene. Collaborator-led incubators are often used to build early relationships with startups through funding, lab space, and technical support. However, revenue upside remains less certain in these arrangements.
- **Test and learn:** Investing in internal development capabilities to support co-development or collaborations with existing biotech companies and research institutions allow for relationship building without investment in a major on-the-ground footprint.

The strategy a given company chooses to deploy is often based on existing footprint; companies with smaller footprints today will likely choose to begin with lower investment strategies. These strategies, of course, are dynamic, with companies moving across approaches and often approaching multiple in parallel.

Regardless of path, success rests on three enablers:

1. Clarity on China's role within an organization's global strategy and overall portfolio strategy
2. Local know-how and boots on the ground – via trusted relationships or in-market capabilities and footprint
3. Institutional confidence and organizational agility to navigate evolving policy and geopolitical dynamics

Engaging with China's innovation ecosystem is no longer a tactical move—it's a strategic choice. Companies that align internal capability with external collaboration are more likely to access China's scientific strength and potentially convert it into a lasting global advantage.

b. Translating access into advantage

China's transformation into a biopharma innovation hub is helping to redefine how global pharmaceutical companies compete for science, speed, and scale. The country now offers differentiated assets, clinical efficiency, and digital sophistication, but competition for access is accelerating. Companies that do not invest in local insight and evaluation risk losing visibility into the most promising innovation. Yet even as reforms have improved predictability, risks remain, including data protection, IP enforcement, and an evolving geopolitical landscape. The right stance, therefore, is one of cautious optimism, to lean into China's growth potential but engage with structured diligence and strategic control.

For companies that engage with structured strategy, China offers tangible ways to create global advantage:

- **Deepen local relationships:** Strengthen ties with universities, hospitals, and regulators to maintain access to emerging science.
- **Leverage trial efficiency:** Use China's Phase 1 and proof-of-concept infrastructure to help accelerate early development and "fail fast."
- **Apply AI and digital insights:** Translate lessons from China's AI-driven R&D ecosystem to global discovery programs.
- **Enhance market sensing:** Use advanced analytics and Generative AI (GenAI)-enabled forecasting to stay ahead of policy and competitive shifts.

Executed effectively, these strategies may turn engagement in China's ecosystem into measurable improvements in R&D productivity, speed, and innovation output.

Capturing value in China requires disciplined collaborator selection and strong governance. Alignment on data integrity, regulatory standards, and technical capability remains essential.

Deal structure can be equally critical. Analysis of deals shows many use a moderate upfront investment with milestone triggers to help protect flexibility and local upside. Meanwhile, cross-border investment scrutiny and potential U.S. technology-transfer restrictions, including Committee on Foreign Investment in the United States (CFIUS) reviews, underscore the need for adaptive compliance[15]. While we've seen a small number of Chinese companies, such as BeOne, being successful at globalizing, many, like Hengrui (GSK), 3SBio (Pfizer), and CSPC (AstraZeneca) still depend on multinational relationships to scale internationally, providing ongoing opportunities for win-wins.

c. Watch-outs and lessons learned

Given the risks inherent to the China market, companies should carefully evaluate different strategies and preemptively deploy mitigation solutions. Challenges faced by organizations in accessing innovation in China offer valuable lessons learned. Strategies may fall short when:

- Global commercialization is not factored into R&D approach, leading to unforeseen development costs and / or lack of acceptance in foreign markets
- Global oversight and compliance pull-through mechanisms of local sites and collaborators are weak, leading to violations and reputational damage
- Dependency on China supply chain, leading to future scalability challenges
- Deal decisions are driven by hype instead of alignment to long-term portfolio strategy, leading to dissynergies and eventual divestment

Proper vetting, trust-building with local participants, and connection of China business development with broader organizational strategic priorities are important to help mitigate downside risk and allow for success in China.

BUILD AND OWN

Building local presence fosters favorability amongst local participants and regulators. Though this approach requires a significant time horizon and long-term commitment, these participants may see advantages in market access for commercialization and tap directly into the advantages of cost-effective R&D in China.

	In-market & In-house development	Operational partnerships
Rationale	• Regulatory relationship building • Patient Recruitment speed • Reduced trial costs and timelines • Guarantees design, data, regulatory control	• Fast, low-risk China access • Rapid proof-of-concept validation • Cost-efficient CRO operations • Broader site/patient reach leveraging CRO network
Success Factors	• Register entity, secure licenses • Hire local leadership teams and build alliances with NMPA regulators • Onboard and train staff; introduce digital tools • Prioritize experienced multinational trial site activation • Establish compliant data systems and align protocols with global and Chinese standards • Implement automated audit trails and local retention	• Establish scorecards for vendor selection/ monitoring, select and vet CRO • Define governance and roles; assign local experts for oversight • Define contract scope and milestones • Establish approach to monitor CRO's compliance and define milestone-based payments • Establish joint SOPs and staff rotations for best practices • Implement routine audits, real-time monitoring to ensure compliance

COLLABORATE AND SCALE

Leveraging local biopharma participants enables speed and comparative flexibility to react to changing market circumstances while accessing local know-how and channels via the established partner. However, loss of control is the trade-off for this flexibility. Having a trusted collaborator is essential for success.

	Entry through acquisition	Expand through licensing
Rationale	• Access to pipelines / assets, talent, manufacturing, platform capabilities • Accelerated market entry • High level of control	• Rapid, cost-effective entry into China • Limit risk with milestone-driven deals • Leverage collaborator scale / local presence while maintaining flexibility
Success Factors	• Conduct diligence on IP, supply chain, liabilities, approval pathways and regulatory hurdles • Align deal teams on strategy, leadership buy-in, and sequence pipeline development to reflect priorities • Identify any integration risks and set early contingency plans for disruptions • Secure, incentivize key local talent • Implement digital data governance, compliance • Engage international regulatory bodies to ensure approval pathways	• Conduct diligence on IP, supply chain, liabilities, approval pathways and regulatory hurdles • Ensure strategic asset fit and ex-China reimbursement viability • Align governance on China/global rights and stand-up and ensure streamlined plans for tech transfer • Establish transparent, multi-level stakeholder engagement, including continuous collaborator management and compliance oversight • Engage international regulatory bodies to ensure approval pathway

TEST AND LEARN

Investing internal development capabilities to support co-development or collaborations with existing biotech companies and research institutions allows for relationship building without investment in a major on-the-ground footprint.

	Joint development	Collaborative research projects
Rationale	• Access to local innovation with top local biotechs • Share investment and development risks • Flexibility to shape relationship and development scope	• Cost-effective access to innovation • Tailor research to China-specific needs • Experiment with new, high-risk platforms • Leverage universities for sourcing, collaboration and scientific networks
Success Factors	• Establish joint governance and integrated teams, including performance milestones and escalation protocols • Align regulatory strategy and milestones • Enable transparent cross-border data sharing, including IP management systems • Align on resources required upfront and embed personnel for integration and adaptation • Codify step-out mechanisms for value protection	• Finalize clear legal and IP frameworks, including future-proof data security protocols • Ensure regulatory readiness and adaptability and allow for real-time project review with agile adjustments • Establish joint scientific review committees and stakeholder engagement approach • Secure ethics and institutional approvals • Implement joint accelerators advancing discoveries to translation

ACCESS AND OBSERVE

Tapping into early-stage innovators allows for a smaller investment while maintaining access to the local innovation scene. Partner-led incubators such as Lilly's Catalyst360 and Sanofi's Intrepid Labs build early relationships with startups through funding, lab space, and technical support. However, revenue upside remains less certain in these arrangements.

	Venture funding	Start-up accelerators
Rationale	• Early pipeline access • Influence research priorities, with minimal investment • Build ecosystem of relationships with key industry participants	• Early pipeline access at minimal risk and investment • Deep partnership building and capability knowledge exchange • Ability to pursue proof-of-concept, validating impact before scaling
Success Factors	• Conduct detailed diligence and align opportunities with business objectives • Structure investment around proven, high-impact solutions • Monitor and address regulatory requirements • Reinforce governance and proactive operational engagement for strong compliance and optimal results • Manage collaboration portfolio for maximum value and ensure flexibility for rapidly changing business aspects	• Embed teams and establish clear partnership agreement roles and expectations to deepen collaboration and speed outcomes • Enable open access and mentorship for faster innovation and development of local talent • Align early on IP and governance for smooth execution • Fast-track commercial readiness with targeted skills • Establish strong controls through clear policies, risk management and identify internal champions to drive collaboration initiatives

Source: Deloitte Global

Conclusion

China's ascent as a biopharma innovator is no longer peripheral—it's central to the global innovation landscape. Access to the ecosystem alone may not create advantage; the differentiator lies in how effectively companies combine local presence, trusted relationships, and strategic agility.

Those that act early, evaluate rigorously, and execute with discipline are likely to be a part of China's growth and help define the next era of global biopharma innovation.

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Endnotes

1. Nature. "China's Biopharma Ambitions: Fast Follower to Fast Leader." Accessed January 2025. https://www.nature.com/articles/d41573-025-00070-6
2. Franklin Templeton. "China Biotech Boom: Fast Follower to Fast Leader." Accessed January 2025. https://www.franklintempleton.lu/articles/2025/equity/china-biotech-boom-fast-follower-to-fast-leader
3. Deloitte. "Cross-Border Data Flow Regulations." Accessed January 2025. https://www.deloitte.com/cn/en/services/consulting-risk/perspectives/cross-border-data-flow-regulations.html
4. Frontiers in Pharmacology. "Emerging Trends in Chinese Biopharma." Accessed January 2025. https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2025.1579037/full
5. PubMed Central. "Innovations in Biopharma: China's Role." Accessed January 2025. https://pmc.ncbi.nlm.nih.gov/articles/PMC12280122
6. Caixin Global. "China's Top Graft Watchdog Announces Year-Long Crackdown on Pharmaceutical Industry." Accessed August 2023. https://www.caixinglobal.com/2023-08-02/chinas-top-graft-watchdog-announces-year-long-crackdown-on-pharmaceutical-industry-102089269.html
7. Fierce Pharma. "Lilly, Innovent Hit FDA No-Go on Discounted PD-1 Immunotherapy's Lung Cancer Bid." Accessed January 2025. https://www.fiercepharma.com/pharma/lilly-innovent-hit-fda-no-go-discounted-pd-1-immunotherapys-lung-cancer-bid-after-bleak
8. BioPharma Dive. "Is 2025 the Chinese Year of Biopharma?" Accessed January 2025. https://www.biopharmadive.com/spons/is-2025-the-chinese-year-of-biopharma/738274/
9. Shanghai Government. "Latest Updates on Biopharma Initiatives." Accessed November 2025. https://english.shanghai.gov.cn/en-Latest-WhatsNew/20251124/32583cf426d44a698a571cf9828752b2.html
10. South China Morning Post. "China's Biotech Hub Suzhou Thriving—Can It Become the Next Boston?" Accessed January 2025. https://www.scmp.com/news/china/science/article/3321794/chinas-biotech-hub-suzhou-thriving-can-it-become-next-boston
11. ASCPT Journal. "Clinical Pharmacology Trends in China." Accessed January 2025. https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.70084
12. ASCPT Journal. "Clinical Pharmacology Trends in China." Accessed January 2025. https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.70084
13. BioWorld. "China Clears More First-in-Class Innovative Drugs Than Ever Before." Accessed January 2025. https://www.bioworld.com/articles/718968-china-clears-more-first-in-class-innovative-drugs-than-ever-before?v=preview
14. Nature. "China's Biopharma Landscape: 2024 Update." Accessed January 2024. https://www.nature.com/articles/d41573-024-00120-5
15. U.S. Department of the Treasury. "Press Release: JY2716." Accessed January 2025. https://home.treasury.gov/news/press-releases/jy2716

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