Reshaping global value

Strategies for Chinese innovative drugs to win in the global market

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Contents

Foreword

At present, the international expansion of Chinese innovative drugs has evolved from a mere "buzzword" into an industrial proposition that must be addressed directly.

If the industry previously discussed whether Chinese innovative drugs could go abroad, the answer today is remarkably clear: China can not only go global but has already become a significant and indispensable supplier within the global innovative drug ecosystem. Whether in next-generation technologies such as antibody-drug conjugates (ADCs), bispecific (BsAb)/multi-specific antibodies, or cell therapies, Chinese developers have demonstrated increasingly strong R&D efficiency, engineering capabilities, and asset output. A growing number of multinational pharmaceutical companies now view China as a key source for Business Development (BD), while more Chinese assets are securing high valuations in global transactions. This indicates that Chinese innovative drugs are no longer merely chasing global innovation; they are beginning to shape it.

However, it is precisely for this reason that Chinese companies must remain clear-headed about expanding overseas rather than viewing it through a romanticized lens.

The greatest reality facing the international expansion of Chinese innovative drugs today is not a lack of opportunity, but rather that the industry has yet to reach its full potential in terms of value. On one hand, the rise of Chinese innovation capacity is an established fact; on the other, the actual global market share, global commercialization capabilities, and global brand influence achieved by Chinese innovative drugs do not match the country's output capacity. While the world has begun to recognize Chinese innovation, the country has not truly established a global value realization system commensurate with this status. In other words, Chinese novel drugs are undergoing a critical leap from high-value R&D transformation to reshaping value—a step far more difficult than simply developing a single product.

Going abroad is no longer an option, but a necessity. This is not merely because European and US markets are larger and have stronger payment systems, nor simply because multinational pharmaceutical firms face patent cliffs and gaps in their portfolios. It is because the Chinese innovative drug industry itself has reached a stage where it must achieve its next leap through globalization. The domestic structural contradiction between intense competition and weak payment systems remains unchanged, while the capital market is reassessing its tolerance for making high-investments into an innovation sector characterized by long cycles. A single market can no longer support the continuous upward trajectory of Chinese novel drugs. For many enterprises, international expansion is not a nice-to-have luxury, but the key variable that determines whether they can survive, stand out, and go the distance.

It is worth noting, however, that going abroad has never been as simple as merely out-licensing a product. In recent years, many firms have viewed the conclusion of a license-out deal as the hallmark of international success. While this perspective was understandable in the early stages, it is now insufficient. The signing of a deal is merely the starting point, not the finish line. Whether clinical trials can proceed smoothly, whether registration can be approved, whether the supply chain can provide support, whether partners can collaborate efficiently, whether commercialization can be realized, and ultimately, whether continuous value can be created for patients—these are the questions that truly determine whether an asset can gain a foothold in the global market. They also define whether a company is merely selling a project or building global capabilities.

Foreword

In other words, the international expansion of Chinese innovative drugs must no longer rely on opportunity but on certainty. This certainty stems first from the product itself. Without sufficiently strong product competitiveness, expansion is built on sand. First-in-class potential, differentiation, robust data packages, and a clear patient value proposition determine whether an asset is qualified to compete in the global market.

However, a deeper level of certainty comes from having a broad range of capabilities. Today, what truly sets companies apart is often not a result achieved in the laboratory, but the full-chain capabilities surrounding the asset: whether the strategic positioning is clear, whether the target markets are chosen correctly, whether partners are a good match, whether the transaction structure is rational, whether clinical development is efficient, whether the registration pathway is forward-looking, whether Chemistry, Manufacturing and Controls (CMC) and the supply chain are globally compliant, and whether the organization and talent can support complex international execution. In the future, competition for Chinese innovative drugs abroad will involve more than scientific teams; it will be a contest between corporate systems.

At this current stage, China's industry needs more than just high-level policy support or the short-term excitement generated by transaction news; it requires deeper insights: precisely what kind of assets are more easily accepted by the global market, which expansion models are better suited to companies at different stages, what cooperation structures can turn short-term deals into long-term value, and what global capabilities constitute a true competitive edge for the next decade.

This is precisely the purpose of this report.

In my view, the international expansion of Chinese innovative drugs has entered a new phase: it is no longer just an adventure for a few leading firms, but the inevitable path toward industrial maturity; it is no longer just a one-off capital event, but is becoming a vital part of the reshaping of innovation systems, the revaluation of industrial assets, and the rearrangement of the global competitive landscape. Those who can understand this change earlier and build expansion capabilities with higher confidence faster will have a greater opportunity to truly transform China's innovative advantages into global competitive advantages.

It is my hope that this report can help the industry advance its understanding of going abroad one step further—from "going out" to "accessing"; from "selling" to "gaining a foothold"; and from "securing a deal" to "reshaping value". This will truly allow Chinese innovative drugs to better benefit patients worldwide.

This endeavor is worthy of our long-term commitment and our most serious consideration.

Liyun Zhou
Founder and Chairman, PharmCube

Executive summary

In 2026, China's biopharmaceutical sector was established as a national emerging pillar industry. This marks a new starting point for Chinese innovative drugs, requiring a transition to the next stage of high-quality development, for which international expansion has become essential.

1. International expansion as an inevitable path for China's innovation industry

At present, China has become the main driver of global innovative drug pipeline growth and has assumed a leadership position in next-generation technologies. While China has become a vital supplier of innovation to the world, a structural contradiction exists between its rising innovation capabilities and its industrial operating environment. This report proposes that international expansion will be the new normal, placing Chinese pharmaceutical innovation at a critical juncture for the reshaping of its global value.

2. Shifting toward diversified portfolio strategies

This report posits that expansion models are evolving from single-product out-licensing to a diversified and strategic mix of pathways. In the long term, multi-layered expansion models will continue to coexist. Independent expansion is the ultimate path to building global capabilities but faces significant capital and operational challenges. Collaborative expansion remains the mainstream choice at this stage and exists at two levels: product licensing and collaborative capability building (such as joint development or NewCo models). This report anticipates that Chinese innovative drugs will enter a global capability-building phase over the next decade.

3. Constructing a winning strategy centered on certainty

In a complex international environment, certainty has become the most critical competitive barrier in cross-border transactions. This report suggests that those capable of constructing certain global development strategies will gain global pricing power. These include:

Product competitiveness is the cornerstone: Multi-National Corporations (MNCs) are increasingly focused on first-in-class or best-in-class assets; simple me-too products no longer have the space to penetrate major markets.

Clinical and registration strategies: Multi-regional clinical trials (MRCTs) should be the default option for global development, as the risk associated with the "China data + bridging study" strategy has increased significantly; regulatory accelerated approval channels should be utilized to shorten time-to-market.

CMC and supply chain compliance: CMC deficiencies are a frequent cause of marketing authorization rejection for Chinese pharmaceutical firms; manufacturing process stability, analytical method validation, and cGMP-compliant supply chain systems are the lifelines of transaction execution.

4. Overcoming systemic geopolitical and regulatory challenges

Surveys indicate that the top three challenges faced by C-level executives are overseas commercialization (86.1%), regulatory barriers (81.0%), and geopolitics (80.3%).

Geopolitical response: There is a need to build resilient global cooperation networks through NewCo models or partnerships with globally reputable service providers, leveraging their compliance systems to endorse internal pipelines.

Strategic value of professional service providers: Companies should shift from cost-based outsourcing to strategic partnerships for capability building, using global compliance-native partners to bridge gaps in overseas resources and compliance experience.

5. Establishing global trust and reshaping global value

This report contends that the essence of the international expansion of Chinese innovative drugs is the transformation of the country’s efficiency into global value. Future victors will be those companies able to deeply integrate the efficiency of Chinese innovation with the certainty of global regulatory endorsement. Expansion is no longer a simple transfer of assets, but a full-chain systemic competition encompassing strategic positioning, product quality, compliant manufacturing, and global operations. Decision-makers should focus on unmet global clinical needs and achieve value reshaping within the global pharmaceutical ecosystem by constructing a high-confidence value chain.

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The global expansion of Chinese novel drugs as a new normal driven by both internal and external factors

Since 2015, China's innovative drug industry has undergone a structural transformation, with significant improvements in innovation capabilities, coupled with systematic enhancements in innovation scale, efficiency, and quality. China has demonstrated global leadership in multi-target products such as antibody-drug conjugates (ADCs), bispecific (BsAb)/multispecific antibodies, and cell therapies, becoming a key contributor to global innovation.

In 2026, the biopharmaceutical industry was officially established as a national emerging pillar industry. With the full-chain policy support for the high-quality development of innovative therapies, the overseas expansion of these products will become a new normal in the industry. This is an inherent requirement for the sector to move toward a high-quality development stage and an inevitable trend driven by both internal and external factors.

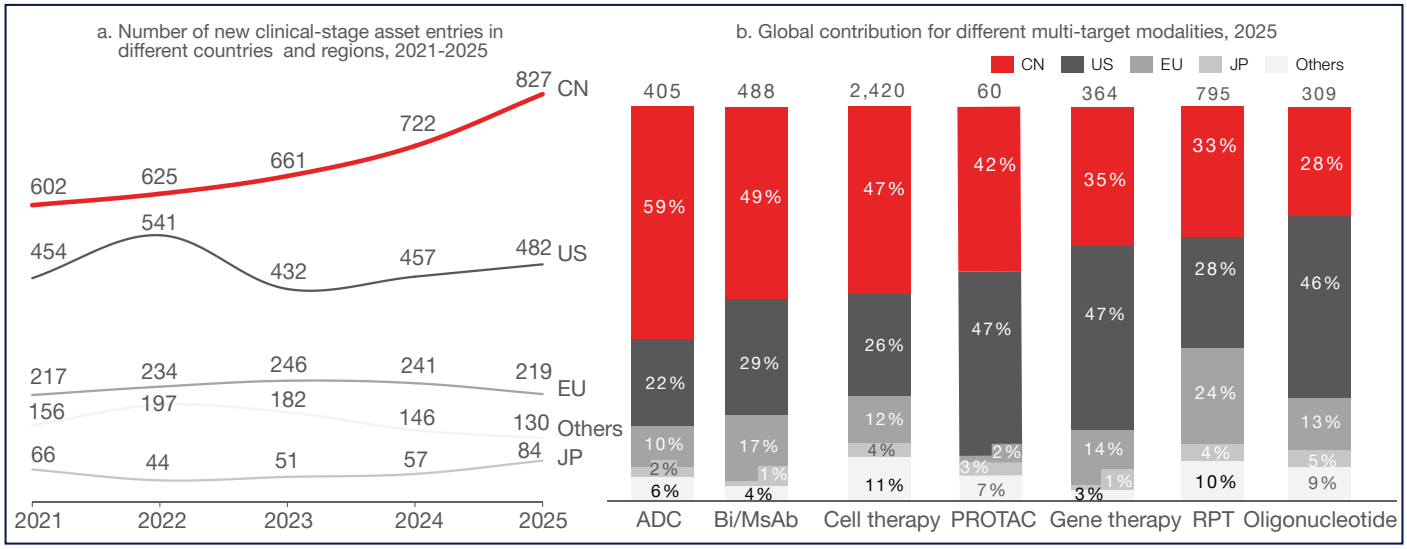
Internally, the structural contradiction between China's rising innovation capabilities and the competitive, low-profit environment of a single market has become increasingly prominent. Driven by survival pressure, enterprises urgently need to pursue global expansion to obtain higher value returns and sustainable R&D funding.

Externally, Europe and the US account for more than 70% of the innovative drug market. Faced with the pressure of patent cliffs and rapid technological iterations, major demand-side players—represented by Big Pharma—maintain a constant hunger for high-efficiency, high-quality innovative assets.

1 China's innovation capability has been significantly enhanced

China's scale of innovation has increased. Since 2015, the number of innovative drugs independently developed by Chinese enterprises has ranked first globally. Statistics show that as of December 31, 2025, there were 14,088 innovative drugs undergoing clinical development[1] worldwide, with China contributing 34% and the US 29%. China has become the core driving force behind the growth of the global innovative drug R&D pipeline, with the number of China-originated new clinical-stage asset entries each year constantly increasing, and accounting for a global share of about 40% in 2025—nearly twice that of the US (Figure 1a). China has already gained a leading position in the innovation of multi-target products, represented by ADCs, BsAbs/multispecific antibodies, and cell therapies, contributing **59%**, **49%**, and **47%** of global innovative ADCs, BsAbs, and cell therapies respectively (Figure 1b). These multi-target products represent the fourth wave of pharmaceutical industry technology, revolutionizing the standard therapies for various diseases.

Figure 1. Number of new clinical-stage asset entries in different countries and regions, and global contribution for different multi-target modalities

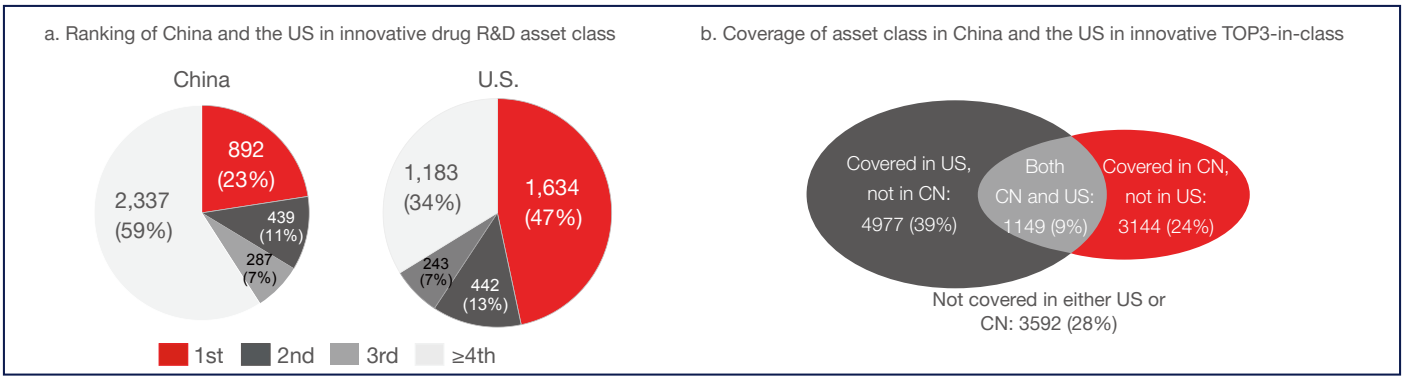


Data source: PharmCube's NextBiopharm database.
Notes: a) FIH clinical trials initiated from 2021 to 2025 for innovative drugs, excluding traditional Chinese medicines and preventive vaccines. FIH time is based on the time of trial disclosure. b) Data cutoff date is December 31, 2025. PROTAC: proteolysis-targeting chimeras; RPT: radiopharmaceuticals.

The following analysis shows that the quality of Chinese innovation continues to improve. Here, drugs with the same target, modality, and mechanism of action (MoA) are grouped into the same R&D asset class. The more advanced a pipeline's progress within its asset class, the more potential first-mover advantage it is considered to have. The industry generally focuses on first-in-class (FIC) products or the top 3 contenders (or TOP3-in-class). The proportion of FIC therapies in China-originated research pipeline is on the rise, currently accounting for 23% of FIC products among the country's innovative drugs in development. Although this figure is lower than that of the US (47%; Figure 2a), the proportion of FIC drugs in China has increased from less than 5% in 2015 to around 30% in 2024[2].

China and the US have good complementarity in R&D asset class coverage (Figure 2b). Statistics show that TOP3-in-class pipelines of China and the US involve 12,862 R&D asset classes. The two countries cover 72% (9,270) of the R&D tracks combined. Among them, 24% (3,144) are covered only by China, while 39% (4,977) are covered only by the US.

Figure 2. Ranking and coverage of China and the US in innovative drug R&D asset class



Data source: PharmCube's NextBiopharm database.
Notes: Only innovative drugs with active R&D status are included, excluding those with unknown targets or mechanisms of action. Data cutoff date is December 31, 2025.

1 from IND to NDA stage
2 PharmCube, China's Innovative Pharmaceutical Industry in a Global Perspective: 10-Year Review and Outlook, March 17, 2025.

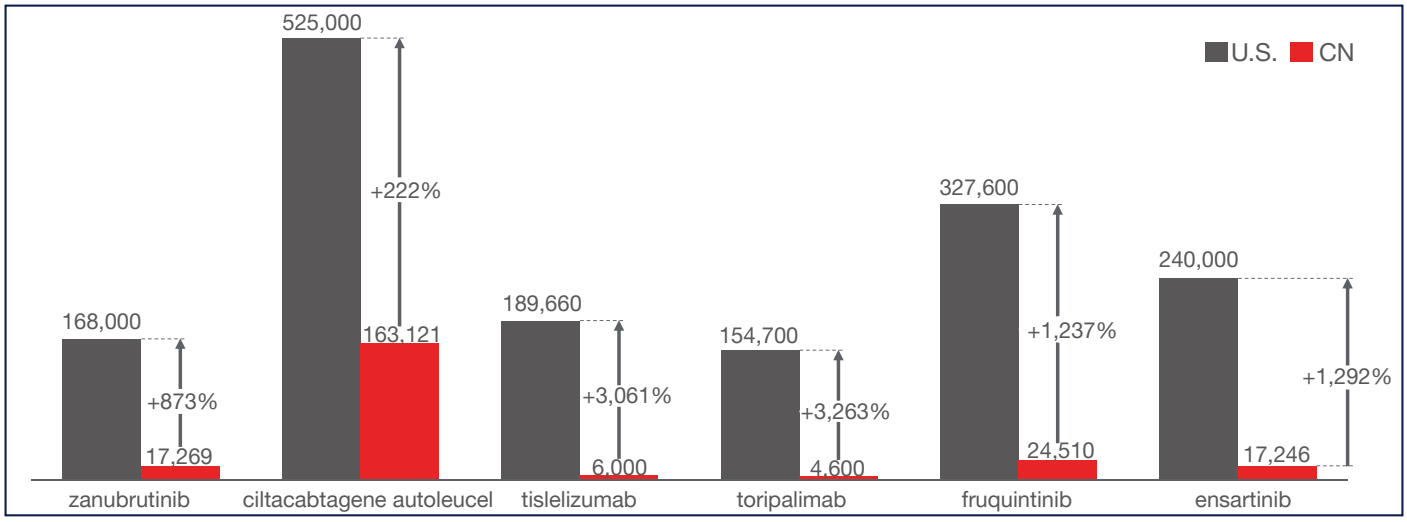
2 With strong competition and low returns, China has not yet established a mature and diversified payment system

Chinese innovative drugs still rely heavily on their domestic market, leading to cut-throat competition. In terms of the concentration of targets in the R&D pipeline, from 2018 to 2025, Chinese innovative drugs first entering human trials covered a total of 843 targets, with popular targets being basically the same as those globally. China's 20 most popular targets covered 1,028 products, with a concentration of 26.7%, significantly higher than the global figure of 18.2%[3]. This intense competition has led to a decline in the return rate of China's innovative drug R&D which, coupled with drug pricing factors, makes it difficult for developers to afford the high R&D costs associated.

There exist two factors leading to low returns.

1) The diversified payment system for innovative drugs is still being improved, with the Basic Medical Insurance Fund (BMIF) remaining the primary payer for drugs[4], SMI (Social Medical Insurance) has always adhered to its core positioning of ensuring basic medical security for all citizens. China's per capita health expenditure is RMB 6,425 per year, approximately one-tenth of the levels in Japan or Europe, and one-sixteenth of those in the US. In terms of the financing structure, out-of-pocket payments and government health expenditure each contribute 27%, while SMI 42% and commercial insurance 4%. The main difference in payment structure between China and the US is that commercial insurance (including private and other third-party insurance plans) accounts for 47% in the US;
2) There is still a significant gap between China's innovative drug pricing and that of developed countries. While SMI entry is the key to market access, many therapies face price reductions of around 50%. In general, drug prices in China are 1/30 to 1/10 of those in the US (Figure 3).

Figure 3. Comparison of annual treatment costs for China-originated innovative drugs in the US and China (USD).



Data sources: Wholesale Acquisition Cost (WAC) data, corporate disclosures, National Healthcare Security Administration (NHSA), online public information.
Notes: Annual treatment cost is calculated from the usage and dosage specified in the drug label; exchange rate: USD 1 to RMB 7.05.

3 PharmCube, China Innovative Drug Development Trends 2025, March 18, 2026
4 PharmCube, Capitalizing the Rewards of R&D: A Decade-Long Panorama of China's Innovative Drug Commercialization, October 15, 2025.

3 The high cost of innovative drug R&D requires diversified funding

The cost of R&D for an innovative drug exceeds USD 2 billion. According to Deloitte's analysis[5], the average research and development cost of a drug from discovery to market launch has jumped from about USD 1.296 billion in 2013 to approximately USD 2.229 billion in 2023, with 50% to 70% of this cost incurred during clinical development. Statistics show that the financing scale of the primary market has remained at USD 5 billion in recent years (Figure 4), which is about 70% lower than the peak of USD 16.3 billion in 2021. Meanwhile, as of the end of 2025, among innovative drug companies established since 2015 that have received financing, the proportion of those that have not received funding for three consecutive years has climbed to 44%. Chinese innovative drug companies are facing survival pressures. Besides biotech start-ups, only 6 or 7 of China's top innovative drug companies, such as Hengrui, BeOne, and Innovent, have a financial reserve[6] of over RMB 10 billion (USD 1.4 billion).

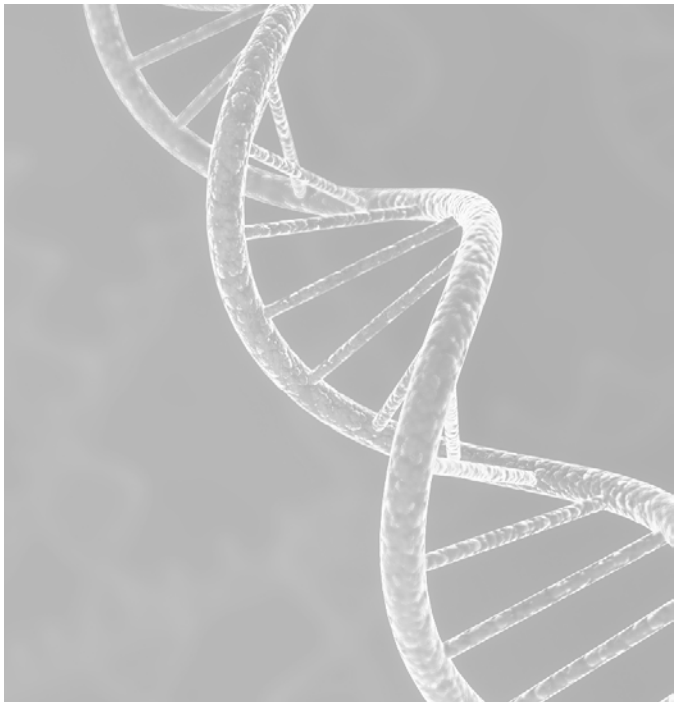
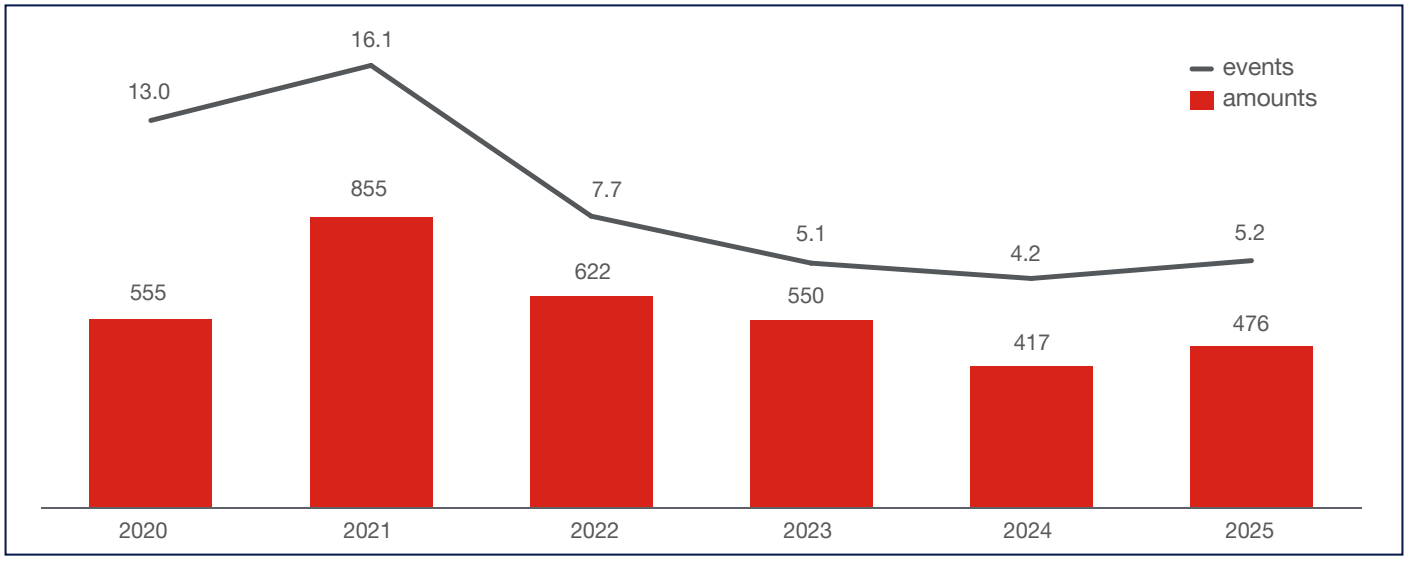


Figure 4. Financing events and amounts (USD billion) in China's primary market for innovative drugs.



Data source: PharmCube's InvestGO database.
Notes: ❶ Data covers from 2020 to 2025; ❷ Innovative drug companies are defined as those engaged in the development of innovative drugs, based on publicly disclosed pipelines or future business plans from sources such as official websites, authoritative news media and official registry platforms; ❸ The regional scope of Chinese innovative drug developers covers Hong Kong, Macao, and Taiwan companies; ❹ Financing events exclude IPOs, M&A, privatizations, and equity transfers. Data cutoff date is December 31, 2025.

Amidst escalating R&D costs and tightening capital constraints, China's innovative drug industry should expedite its transition into a stage of realizing global value. Whether it's start-up biotech firms or domestic leaders, solely relying on the local financing environment and domestic market can no longer sustain highly active, multi-pipeline global R&D investment over the long term. In this context, the licensing of innovative drugs for overseas markets has evolved beyond being merely a business expansion strategy. It has gradually become one of the key pathways for companies at this stage to share R&D risks, diversify funding sources, and reshape innovation value.

5 Deloitte, Be brave, be bold. Measuring the return from pharmaceutical innovation. March 2025.
6 Corporate announcements; "Financial reserve" refers to assets held by the enterprise in monetary form, specifically consisting of cash and cash equivalents, restricted cash, and fixed-term deposits.

4 With biopharmaceuticals listed as an emerging pillar industry, policies for innovative drug globalization continue to improve

As mentioned above, although Chinese innovative drugs have seen significant improvements in scale and quality, they are highly dependent on the domestic market, leading to cut-throat competition and a single payment approach. In the new phase, policies are continuously promoting the high-quality development of innovative drugs and fostering global competitiveness.

Firstly, the country has selected biopharmaceuticals as an emerging pillar industry. In the Government Work Report released on March 5, 2026, biomedicine was listed alongside integrated circuits, aerospace, and low-altitude economy for the first time, explicitly stating that it should be developed into an emerging industry pillar and clearly requiring the promotion of high-quality development of innovative drugs and medical devices. Since 2024, China's State Council and local governments have issued policies supporting the full-chain development of Chinese innovative drugs (as shown in the table below), encouraging the global development of innovative drugs, improving the convenience of the import and export of goods, supporting global registration and certification of innovative products, and facilitating international exchanges and cross-border transactions.

Table 1. Core policies for the global expansion of Chinese innovative drugs.

Department	Release date	Policy document	Main content
State Council	July 2024	Implementation Plan for Supporting the Development of Innovative Drugs Across the Entire Chain	Coordinates policies on pricing, SMI, commercial insurance, and investment/financing; optimizes review and approval processes. **Promotes a comprehensive national support system**, mobilizes R&D resources, and strengthens basic research to build a solid foundation for long-term growth.
State Council	Jan 2025	Opinions on Comprehensively Deepening the Reform of Regulation of Drugs and Medical Devices to Promote the High-Quality Development of the Pharmaceutical Industry	Deepens reform across the entire regulatory lifecycle; accelerates the creation of a unified national market; **builds a globally competitive innovation ecosystem to** transition China from major to strong pharmaceutical nation. **Supports expansion of international cooperation**, such as the implementation of ICH standards, support for MRCTs (Multi-Regional Clinical Trials), accelerated accession to PIC/S, and exploration of cross-border fragmented manufacturing of biologics.
NHSA, National Health Commission (NHC)	Aug 2025	Measures for Supporting the High-Quality Development of Innovative Drugs	Facilitates the expansion of innovative drugs into global markets; encourages qualified regions to explore building **global trading platforms for innovative drugs** targeting Southeast Asia, Central Asia, and Belt and Road countries. Supports innovative drug developers in leveraging the unique advantages of Hong Kong and Macau to promote Chinese innovation globally.
State Council	March 2026	Government Work Report	Aims to build emerging pillar industries including integrated circuits, aerospace, **biopharmaceuticals**, and the low-altitude economy; promotes the high-quality development of innovative drugs and medical devices; introduces the Commercial Health Insurance Innovative Drug List (CHIIDL).

Secondly, the country is continuously building national-level support platforms. For example, China's National Healthcare Security Administration (NHSA) has launched the China Drug Price Registration System and a regional centralized procurement trading platform. The price registration system provides official endorsement for domestic drugs entering the global market, helping Chinese innovative drugs obtain reasonable pricing space in overseas negotiations.

A third framework involves regulatory internationalization and legal protection. The official document Opinions on Comprehensively Deepening the Reform of Drug and Medical Device Regulation to Promote High-quality Development of the Pharmaceutical Industry points out the need to continuously promote the implementation of ICH (International Council for Harmonisation) practices, support international multicenter clinical trials, accelerate the process of joining PIC/S (Pharmaceutical Inspection Cooperation Scheme/ International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use), and explore the cross-border segmented production of biological products.

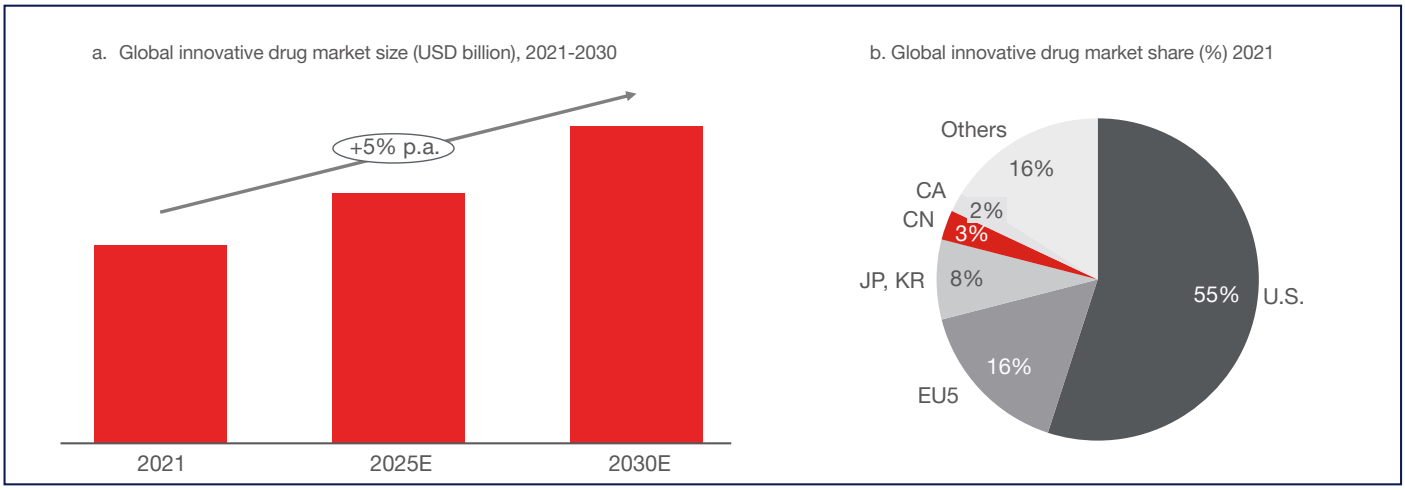
Lastly, the government is spurring the industry also through risk hedging. The document Several Measures to Support the High-quality Development of Innovative Drugs cultivates patient capital to support innovation by developing the commercial health insurance sector and establishing various industrial Fund of Funds (FoF), hedging the financial pressure brought by the high risks associated with going global.

5 Europe, US remain the dominant markets for innovative drugs, with Big Pharma as the primary demand side

As the global innovative drug market surpasses USD 1 trillion (Figure 5), it is projected to maintain a steady growth trend from 2021 to 2030, with a compound annual growth rate (CAGR) of around 5%. **The US and the EU5 (Germany, France, Italy, Spain, and the UK) remain the mainstream markets,** representing 55% and 16% of the market share respectively. In contrast, China's global market share for innovative drugs remains below 5%, with a market size of approximately RMB 250 billion (USD 35 billion).

Big Pharma is the primary demand side. According to Evaluate Pharma statistics[9]: between 2026 and 2030, the top 25 pharma giants will see over USD 300 billion in cumulative market value exposed to patent expirations, with approximately USD 50 billion at risk annually (Figure 6), as shown in the figure below. Under the dual pressures of patent cliffs and rapid technological iteration, Big Pharma is eager for high-efficiency, high-quality innovative assets to stabilize business growth. As China has become a global leader in multi-target product innovation, it is clear that the country has emerged as the most critical business development (BD) sourcing destination for top-tier pharmaceutical companies, both in terms of transaction volume and deal value.

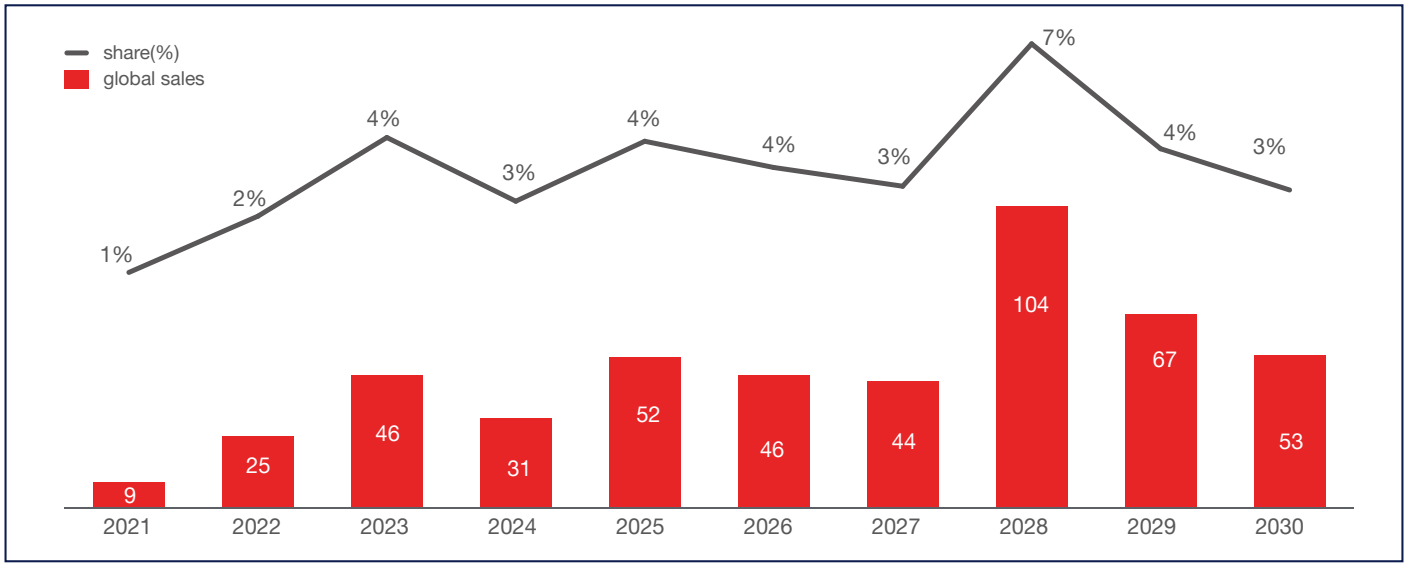
Figure 5. Global innovative drug market: Size (USD billion) and market share



Data sources: Frost & Sullivan report[7], Boston Consulting Group (BCG)[8].
Note: EU5 includes Germany, France, Italy, Spain, and the UK.

7 Market Research Report on Pharmaceutical R&D Outsourcing Services, 2023
8 BCG. Setting Sail (Part II): Chinese Innovative Drugs Going Global Is Inevitable Despite Challenges. BCG China Insights, 2023. (Originally published in Chinese)
9 2025 World Preview:Pharma Growth Steady Amid Turbulent Seas and Rising China.

Figure 6. Evolution of top 25 pharmas' drugs facing patent cliff from 2016 to 2030: global sales (USD billion) and share of top 25 pharmas' total sales.



Data source: 2025 World Preview:Pharma Growth Steady Amid Turbulent Seas and Rising China, Evaluate Pharma.

Chinese innovative drugs are at a critical inflection point for global value transformation. As China's innovation capabilities continue to mature, the overseas expansion of innovative drugs has become an inevitable path toward high-quality development and the reshaping of China's global value proposition. For Chinese enterprises, expansion into international markets means more than just breaking through the structural constraints of a single domestic market; it represents a commitment to undergoing high-standard regulatory scrutiny and market validation on a global stage.

For the global innovation ecosystem, China has already become a key value provider. To fully leverage its innovation potential, China's role in the global industry chain must be redefined to expedite the delivery of Chinese breakthroughs to patients worldwide. Expanding overseas is no longer a simple one-off asset licensing deal; it has evolved into a systemic capability. This capability framework focuses not only on asset quality but also on strategic elements such as collaboration models and regulatory pathways. More importantly, it emphasizes global operational excellence across clinical development, manufacturing, and commercialization.

Consequently, the core challenge of a winning global strategy lies in how to select the most appropriate pathway—tailored to different developmental stages, asset characteristics, and target markets—to transform China's innovation speed, R&D efficiency, and cost advantages into sustainable global competitiveness. This remains the central theme for globalization strategy and practical execution.

02

Primary models and current status of Chinese innovative drugs going global

Expanding into international markets has become an inevitable choice for Chinese pharmaceutical companies to realize the global value of their products and achieve sustainable growth. Currently, models for going global are categorized into two primary types: independent expansion and collaborative expansion (as shown in the table).

1. **Independent expansion:** Relies entirely on the company's internal capabilities to conduct overseas clinical trials. It also requires building in-house overseas regulatory, market access, and commercialization teams to manage the product's launch and sales.
2. **Collaborative expansion:** Relies heavily on the capabilities of overseas partners. The mainstream model centers on asset out-licensing. In recent years, the NewCo model has gained favor among domestic companies due to its unique advantages.

At this stage, while out-licensing remains the primary route for Chinese innovative drug developers, the pathways are becoming increasingly diversified and strategic. The following table outlines the key characteristics of independent versus collaborative expansion.

Table 2. Key characteristics of the different models for overseas expansion.

	Independent expansion	Collaborative expansion		
	Independent expansion Independent global development and commercialization	**Asset out-licensing** Out-Licensing for global rights	**Co-development** Joint global development and co-commercialization	**NewCo** Asset spin-off, venture financing, and collaborative global expansion
Description	Establish organic, end-to-end capabilities in target markets, spanning clinical development and manufacturing to full-scale commercialization	Transfer territorial rights of an innovative asset; the partner independently manages development and commercialization, assuming all costs and capturing all returns	Form regional partnerships to jointly execute clinical development or commercialization, sharing both risks and rewards	License asset rights to a newly formed overseas entity; leverage global capital and strategic partners to build an international management team for global advancement
Key features	• Full retention of asset rights • Requires long-term, sustainable, and substantial capital expenditure • Building an in-house international team to manage the full lifecycle	• Transfer of asset rights in exchange for upfront/ milestone payments or equity • Leveraging the partner's established infrastructure to accelerate market entry	• Transfer of asset rights in exchange for upfront or milestone payments or equity • Formation of a Joint Development Committee (JDC) to co-manage clinical or commercial milestones and risk-sharing	• Transfer of asset rights to the NewCo for cash and equity stakes • Involvement of global funds or strategic partners to co-build the management team and drive globalization
Strategic landscape	Relatively limited adoption at the current stage	The predominant modality in the current market	An emerging trend representing a critical evolution in China's global capability building	A growing and diversified pathway for the globalization of Chinese innovation
Representative cases	BeOne's Brukinsa is a hallmark success	The licensing agreement between 3SBio and Pfizer for SSGJ-707	The 2025 partnership between Takeda and Innovent for the next-gen IO therapy IBI363	Multiple NewCo collaborations by Kevmed Bioscience, such as the deal with Ouro

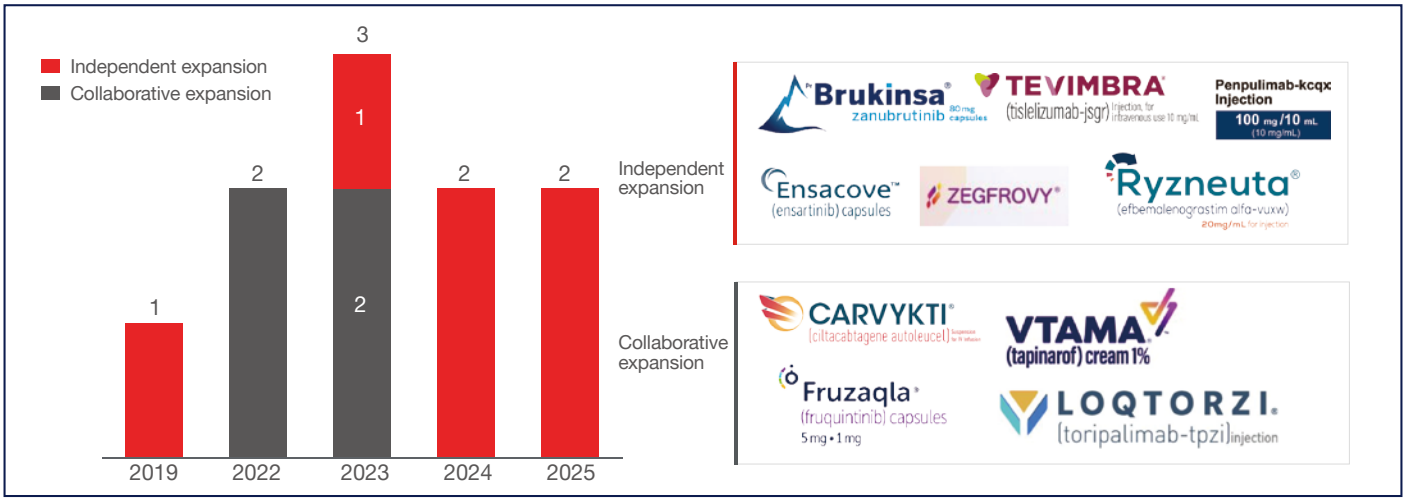
1 Independent expansion: The ultimate path to globalized innovation capabilities

Independent expansion is currently the most challenging model. Under this approach, Chinese enterprises must build full-chain capabilities in target markets—spanning clinical development and manufacturing to commercialization. This requires long-term, continuous, and massive capital support. At present, only a handful of top-tier Chinese biotechs and leading pharmas are exploring this path, with very few products having successfully achieved overseas listing and commercialization.

The synchronized global development of Chinese innovative drugs is still in its infancy. Currently, independent expansion is only suitable for leading Chinese firms with strong financial reserves and relatively mature international operational capabilities. The global development capacity of Chinese pharmaceutical companies requires continuous cultivation.

Statistics show that 567 original Chinese innovative drug pipelines have entered clinical trials in the US, accounting for 10.4% of all 5,422 Chinese clinical-stage innovative pipelines[10]. To date, 10 China-originated drugs have received US approval. Among them, Zanubrutinib is the quintessential representative of independent expansion, followed by others such as tislelizumab, ensartinib, and sunvozertinib (Figure 7).

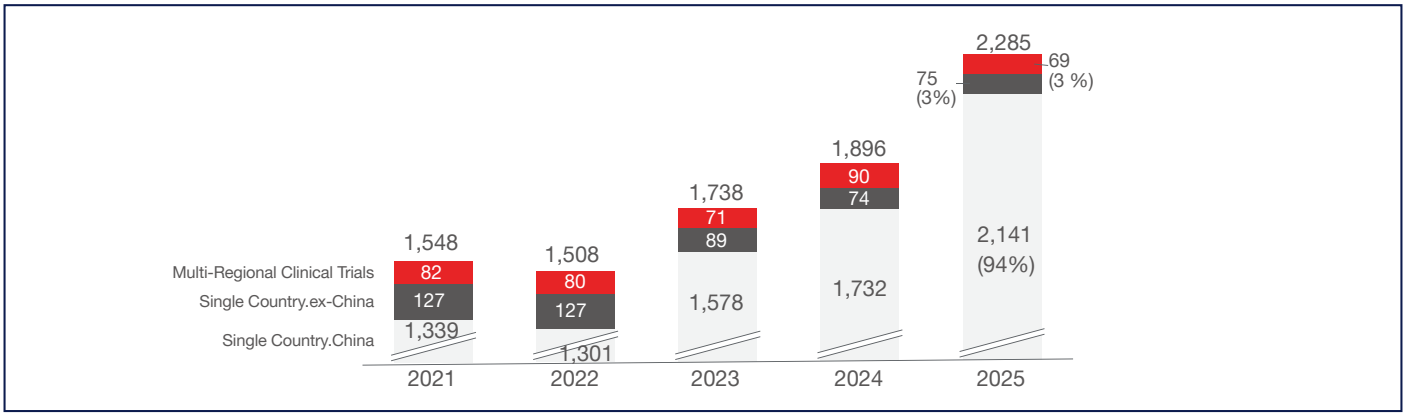
Figure 7. US approvals for China-originated innovative drugs, 2019–2025



Data sources: PharmCube's NextBiopharm and TrialiCube databases.
Notes: Includes innovative drugs originally developed by Chinese companies; data cutoff date is December 31, 2025.

While the number of innovative drug trials initiated by Chinese firms is growing rapidly year-on-year (Figure 8) with over 2,000 trials launched in 2025, 94% of these trials are conducted in Mainland China, with only approximately 6% occurring in overseas regions. Contract Research Organizations (CROs) are key partners in the trial process. Representative Chinese CROs include Tigermed, Kunxiang, and Pharmaron; leading overseas CROs include Thermo Fisher Scientific (which acquired PPD in 2021), IQVIA, and Fortrea.

Figure 8. The geographic distribution of clinical trials initiated by Chinese sponsors



Data source: PharmCube's TrialiCube database.
Notes: Data covers Phase I–III studies initiated by Mainland China companies and disclosed between 2021 and 2025.

10 PharmCube's NextBiopharm database, innovative drug pipelines in active Phase I–III trials, including only assets originated from Mainland China.

2 Collaborative expansion: The mainstream choice at present

Collaborative expansion is currently the most prevalent and mainstream model. In this approach, Chinese firms transfer the development rights of innovative drug assets to partners in exchange for capital, equity investment, or other returns. This strategy has become increasingly diversified in terms of rights transferred and the specific model. Common forms include:

a. Asset out-licensing: The transfer of specific rights to an innovative drug asset. The partner independently conducts clinical development and commercialization, bearing all development costs and retaining all returns.

b. Co-development: Both parties form a regional partnership to leverage their respective strengths and values. They jointly complete clinical development or commercialize the product in the licensed territory, sharing both development risks and commercial rewards.

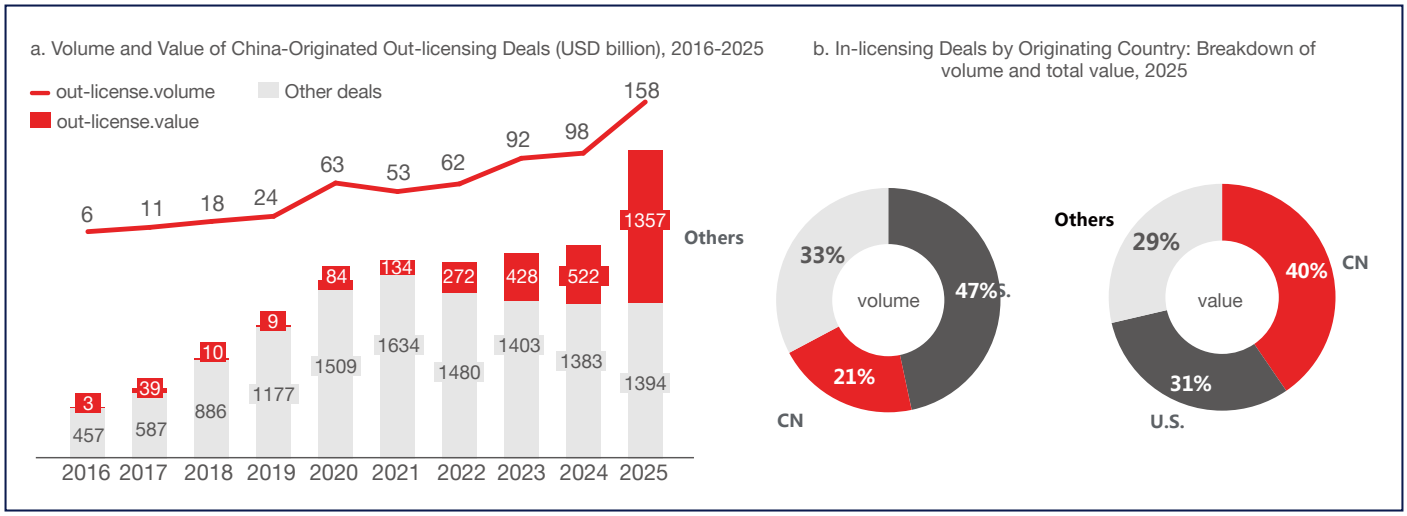
c. NewCo model: Rights are typically licensed to a newly established overseas company. By bringing in overseas funds or strategic partners and building an international management team, the parties jointly drive the global growth of the venture. This is an emerging collaborative model that synergizes pharmaceutical expertise with capital for optimal asset allocation.

China has become a vital global supplier of innovative drugs. With continuous breakthroughs in the scale, quality, and efficiency of its drug development, China has emerged as one of the leading regions for asset transfers.

Statistics show that the volume and scale of out-licensing transactions by Chinese firms have reached record highs. In 2025, deals involving Chinese companies reached 158 transactions, with a total value of USD 135.7 billion. This accounted for 49% of the global deal value of USD 275.1 billion (Figure 9a).

Notably, China has become a key supplier for Big Pharma. In 2025, assets originating from China accounted for 21% by volume and 40% by value of all in-licensing deals made by the top 20 pharma majors (Figure 9b).

Figure 9. Chinese innovative drug out-licensing deals, and Big Pharma in-licensing transactions



Data source: PharmCube's NextBiopharm database.
Notes: Data includes transactions involving innovative drugs and technology platforms only, excluding traditional Chinese medicines, preventive vaccines, generics, modified new drugs, and biosimilars. Data includes Mainland China deals only, excluding Hong Kong, Macau, and Taiwan. Top 20 MNCs refers to the top 20 research-based companies by pharmaceutical sales. Data cutoff date is December 31, 2025.

Quotes of experienced buyer

Reflecting on the Chinese innovative drug industry over recent years, I feel that we have reached a pivotal turning point.

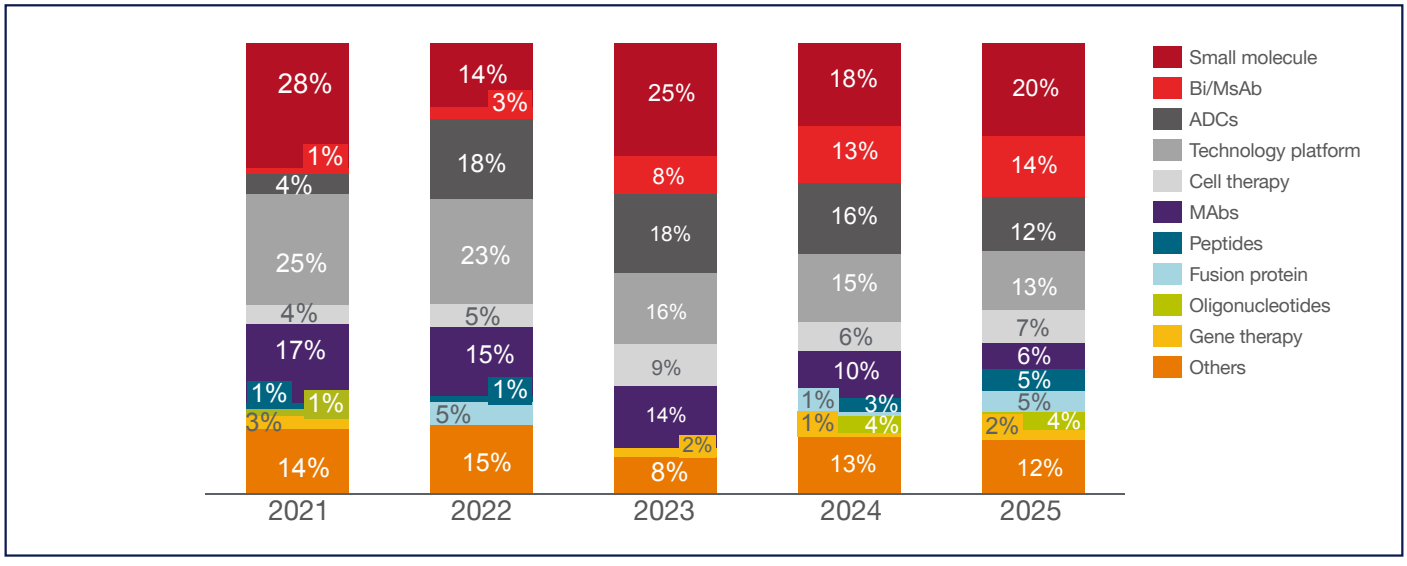
From "whether we can expand abroad" to "how we can sustain global expansion". In the early years, the question was simple: can Chinese innovative drugs go global? That question has now been answered. However, the more difficult challenge is how to deliver products to patients worldwide in a manner that is sustainable, high-quality, and scalable.

This requires not only the collaboration of capital and scientists but also patience. Established global pharmaceutical giants have spent decades consistently implementing standards, building systems, and accumulating trust. This is precisely where many of our enterprises are currently learning and striving to catch up.

— Head of China innovation center at an MNC

ADCs, BsAbs/multispecific antibodies, and other multi-target products account for most of China's out-licensing activity. As previously noted, Chinese pharmaceutical companies have developed internationally competitive platforms and products in fields such as ADCs, BsAbs/multispecific antibodies, and cell therapies, emerging as leaders in the industry's fourth wave of technology. From 2021 to 2025 (Figure 10), the breakdown of Chinese out-licensing deals by project type shows that traditional drugs—including small molecules and monoclonal antibodies (mAbs)—have maintained a stable share of approximately 30%. Conversely, the proportion of multi-target products has increased rapidly, rising from 13% in 2021 to 39% in 2025. ADCs and BsAbs/multispecific antibodies account for a particularly high share, with blockbuster deals occurring frequently. Leading ADC-focused companies, such as Kelun-Biotech, DualityBio, and Biocytogen, have emerged as the top players in terms of the number of out-licensed assets.

Figure 10. Chinese innovative drug out-licensing deals, and Big Pharma in-licensing transactions



Data source: PharmCube's NextBiopharm database.
Notes: Data includes transactions involving innovative drugs and technology platforms only, excluding traditional Chinese medicines, preventive vaccines, generics, modified new drugs, and biosimilars. Data includes Mainland China deals only, excluding Hong Kong, Macau, and Taiwan. "Top 20 MNCs" refers to the top 20 research-based companies by pharmaceutical sales. Drugs without a clearly defined antibody type are categorized as "Others". Data cutoff date is December 31, 2025.

Co-development and the NewCo model represent diversified options for the out-licensing of innovative drugs. These two models place relatively high demands on a company's capital and international operational capabilities; consequently, such cases are currently limited.

Co-development is a deeply integrated model of shared risks and rewards. A representative example is the 2025 agreement between Takeda and Innovent Biologics regarding next-generation immuno-oncology (IO) therapies and ADC collaborations. In this partnership that includes options for assets IBI363, IBI343, and IBI3001, Takeda issued an upfront payment of USD 1.2 billion (including a USD 100 million equity investment), with potential milestone payments of up to USD 10.2 billion. Under the terms for the IBI363 project, Takeda obtained exclusive commercialization and manufacturing rights outside Greater China. The parties will jointly develop IBI363 globally and co-commercialize it in the US, with Innovent and Takeda sharing development costs and commercial profits at a 40/60 ratio. This collaboration represents a strong match between Innovent's R&D capabilities in IO/ADCs and Takeda's global development and commercialization expertise, which will accelerate the global development of IBI363.

The NewCo model is an approach that synergizes pharmaceutical companies with capital to achieve optimal asset allocation. Statistics show that Chinese developers have reached a total of 21 overseas NewCo transactions to date. Keymed Biosciences is a representative firm of this model, having completed four such deals. In November 2024, Keymed entered into a licensing agreement with Platina Medicines (a subsidiary of Ouro), granting Platina exclusive global rights to develop, manufacture, and commercialize the BsAb CM336 outside Mainland China, Hong Kong, Macau, and Taiwan. Keymed received an upfront and near-term payment of USD 16 million, potential milestones of USD 610 million, and approximately 15% equity in Ouro, which was incubated by GSK and Monograph Capital. In January 2025, Ouro completed a USD 120 million Series A financing round led by TPG, NEA, and Norwest, with CM336 as its core asset. In March 2026, Gilead announced the acquisition of Ouro for USD 2.175 billion; as a result, Keymed received an upfront payment of USD 250 million and contingent milestone payments of up to approximately USD 70 million.

Different expansion models entail vastly different capability thresholds, risk structures, and value distribution schemes. Independent expansion allows for the maximum retention of product value, yet it requires a company to possess full-chain global capabilities and demands long-term, stable capital investment. Out-licensing currently remains the most pragmatic pathway, enabling rapid value realization at a lower cost; however, its core challenges lie in asset valuation, deal negotiation and design, and regional synergy. Emerging models, such as co-development and the NewCo approach, combine the advantages of capital, industry expertise, and global operational synergy, but they place higher demands on a firm's international collaboration, organizational governance, and resource integration capabilities.

The biopharmaceutical industry has established itself as one of China's emerging pillar industries. Development over the coming decade must revolve around the globalization of its innovation capabilities, where expansion pathways and models will gradually evolve and coexist in the long term. Collaborative expansion should not merely be a means to supplement cash flow; it should be used to progressively enhance core capabilities in R&D, regulatory affairs, and commercialization, laying the foundation for independent Internationalization. Going global is no longer a race between single products, but an integrated competition encompassing asset quality, expansion strategy, global operational capacity, and risk management. Therefore, the key for Chinese innovative drugs to succeed internationally lies in constructing a strategic and practical framework that is stage-appropriate, risk-controlled, and value-maximized, based on their own development stage, asset characteristics, and target markets.

03

Adding certainty to a winning expansion strategy

Over the past five years, the narrative of Chinese innovative drugs' overseas expansion has undergone a fundamental, yet quiet, transformation. In the early stages, the industry viewed the successful execution of a licensing deal as the benchmark for international competence; today, the evaluation system has shifted toward whether a deal can be successfully executed, whether clinical trials can progress, whether regulatory approval can be secured, and ultimately, whether value can be delivered to patients. In the current environment of complex geopolitics and regulations, certainty has become a scarce asset in international transactions. This certainty stems not only from the scientific advantages of the product itself, but also from the efficiency of clinical development, the global compliance of CMC (Chemistry, Manufacturing, and Controls), and the resilience of the supply chain.

This chapter provides an integrated analysis of how Chinese innovative drug developers can build a winning system of high certainty across ten dimensions, ranging from strategic positioning, product construction, partner selection, and deal design, to clinical execution, regulatory planning, and supply chain development.

1 The starting point for expansion

Developing an expansion strategy must first answer the fundamental questions of **why a company is going global, and what it hopes to achieve.** The international transformation for Chinese innovative pharmaceutical companies is by no means a one-track path. Differences in scale, development stage, resources, and strategic vision dictate the diversity of motives and strategies.

1.1 Biotechs: Value discovery driven by survival

For most biotechs that do not yet possess a fully closed-loop commercialization capability, the primary purpose of going global (particularly through asset licensing) is to **quickly generate cash flow to** fund the R&D of core pipelines. Against a backdrop where domestic medical insurance focuses on basic coverage, homogenous competition is intensifying, and financing channels are narrowing, international expansion has become a pathway for firms to break through valuation ceilings and secure the funds necessary for survival. A successful license-out transaction can bring in substantial upfront and near-term milestone payments, substantially easing cash flow pressures while providing international validation for subsequent financing rounds.

In 2025, the total upfront payments from license-out deals by Chinese pharmaceutical enterprises reached USD 7 billion, exceeding primary market financing for the first time. License-out transactions have thus become a blood transfusion channel for innovative firms. This phenomenon reflects the survival pressures on Chinese biotechs in the current financing environment, where the urgency for cash flow has forced a focus on short-term negotiation strategies. Even for companies eager for rapid monetization, there is a growing realization that maximizing upfront payments may compromise the execution guarantees of contractual terms—and it is the latter that remains the core variable in determining the long-term realization of a deal's value.

1.2 Biopharmas: Sharing risk and leveraging global R&D synergy

For mature innovative pharmaceutical companies that have established a pipeline of significant scale—such as Innovent Biologics, BeOne, and Junshi Biosciences—the strategic objectives for international expansion are more diverse. On one hand, they implement co-development models to distribute the development costs of high-risk, late-stage clinical assets; on the other, they leverage their partners' global commercialization networks to achieve rapid market penetration. Simultaneously, they gain international operational experience and regulatory expertise throughout the collaboration.

1.3 Chinese big pharmas: Global brand building and market diversification

Table 3. Comparison of expansion strategies for different sizes of Chinese innovative pharmaceutical firms

	Biotech	Biopharma	Chinese Big Pharma
Key objectives	1. Rapidly secure upfront payments to improve finances 2. Share late-stage development risks 3. Value validation 4. Expand capabilities	1. Cost-sharing to reduce capital pressure 2. Leverage global commercialization networks 3. Gain international operational experience	1. Global brand building 2. Development of independent commercialization capabilities 3. Maximizing asset value; 4. Strategic resilience
Transaction model	Asset licensing / NewCo	Asset licensing / co-development / NewCo	Asset licensing / NewCo / independent expansion
Negotiation priorities	Upfront payment size > Total deal value > Expanding capabilities	Cost-sharing ratio > Decision-making rights > Revenue sharing	Retention of control > Long-term returns > Brand endorsement
Representative case	Biokin-BMS (2023, USD 800m upfront payment)	Innovent-Takeda (2025, 40/60 cost-sharing)	Hengrui-GSK (2025, USD 12.5b total value)

For traditional large-scale pharmaceutical firms like Hengrui Pharmaceuticals, Sino Biopharmaceutical, and CSPC Pharma, international expansion carries the mission of long-term brand globalization and business diversification. Their strategic aim is to **construct a genuine multinational operational system and a global brand.** When it comes to expansion models, these enterprises tend to prefer co-development arrangements—where they retain more control—or to explore independent expansion. This approach is intended to secure larger profit margins from product commercialization in the mainstream markets of Europe and the US, while gradually establishing a global network for registration, market access, and sales.

Expansion strategies must be aligned with a company's resources and stage of development. Differing objectives for international expansion dictate fundamental differences in resource allocation priorities, partner selection logic, and risk tolerance. Defining a clear strategic positioning is the logical starting point for constructing any global expansion strategy.

Case study

Biokin-BMS: A jump in value following record-breaking upfront payments

In December 2023, Biokin licensed its bispecific ADC asset, BL-B01D1, to Bristol Myers Squibb (BMS) for an upfront payment of USD 800 million, setting a record at the time for the highest upfront payment for a single-asset license-out deal by a Chinese pharmaceutical firm. With this transaction, Biokin achieved a turnaround to profitability, and BL-B01D1 has since commenced over 30 registrational trials globally. Following the success of the deal, the company saw its market capitalization surpass RMB 150 billion (USD 21.3 billion) at one point, and completed a private placement of over RMB 3.7 billion (USD 525 million) in 2025.

2 Building product competitiveness

Regardless of the chosen expansion model, product competitiveness remains the core prerequisite for going global. Without it, even the most sophisticated deal design is built on sand. The competitive landscape of the global biopharmaceutical market is highly stratified; in crowded spaces such as PD-1 antibodies, global competition has become fierce, leaving almost no room for "me-too" products to break into the mainstream markets of Europe and the US. Multinational corporations (MNCs) are increasingly focusing on three types of assets: **first-in-class (FIC) molecules with entirely new targets or mechanisms; best-in-class (BIC) candidates that demonstrate significant differentiated advantages in crowded fields; and platform-based assets featuring innovative technologies or combination strategies.**

2.1 Innovation: The ultimate scarcity premium

FIC drugs represent entirely new mechanisms of action, enjoying longer periods of market exclusivity and greater pricing power. In global BD transactions, FIC assets consistently command higher valuation premiums. In frontier fields such as ADCs, BsAbs, and cell therapies, Chinese innovative drugs are emerging with genuine FIC potential.

Key elements for building FIC competitiveness include: mechanism innovation (scientific validation based on new targets or mechanisms), clinical data irreplaceability (being the first to prove efficacy in late-line patients where no standard of care exists), and extending the time window (establishing a lead through clinical efficiency).

2.2 Differentiated advantage: Moving from "different" to "better"

In the current "red ocean" of me-too drugs, differentiation is the only pathway to establishing a premium. MNCs are becoming increasingly stringent in their criteria for judging innovation, focusing more than ever on the pursuit of BIC status. **This elevated standard poses a significant challenge to Chinese firms that initiated projects using a fast-follow strategy, while simultaneously forcing domestic enterprises to focus more on mechanism innovation during early-stage R&D.**

Differentiation can manifest across multiple dimensions: efficacy and safety (for example, BeOne's zanubrutinib proved superior to ibrutinib in head-to-head trials), administration convenience (upgrading from intravenous infusion to subcutaneous injection), and combination therapy potential (becoming a cornerstone drug for immuno-oncology).

The breakthroughs made by Chinese pharmaceutical firms in emerging technology platforms in recent years are gradually establishing true global differentiated competitiveness. In the ADC sector, for instance, innovations in linker-payload technology by companies such as Kelun-Biotech and DualityBio have attracted significant attention from Big Pharma and led to collaborations with companies like MSD and GSK.

> ***Quotes of experienced buyer***
>
> Recent cases demonstrate that the primary reasons for MNCs handing back deals include scientific issues (such as efficacy failing to meet expectations), strategic realignments within the MNC (such as narrowing focus to core therapeutic areas), and disputes over data transparency (such as Chinese clinical data being biased toward positive results).
>
> — Scientific Project Manager at an MNC

2.3 A solid clinical data package: The hard currency of trust

In expansion negotiations, the quality of the clinical data package directly dictates the buyer's willingness to bid and the overall valuation level. High-quality translational medicine data, a clear biomarker strategy, and standardized early-phase clinical data form the core of a buyer's due diligence. The following factors are critical:

Data quality and regulatory compliance: The standardization of data collection, the establishment of Independent Data Monitoring Committees (IDMCs), the transparency of biostatistical analysis, and the traceability of raw data are all vital components of an MNC's due diligence. Several industry veterans have noted that a primary reason MNCs have returned Chinese products in recent years is the suspicion that domestic clinical data "reports only the good news and hides the bad". Specifically, there is often inadequate disclosure of adverse data, coupled with concerns regarding the independence of investigators. Once doubts regarding data quality arise, deals typically collapse during the technical negotiation stage.

Global comparability of trial design: Differences exist between Chinese and Western patient populations and standard of care (SOC) protocols. Phase III data based solely on Chinese populations often face concerns regarding their extrapolation to other groups during FDA or EMA reviews. Consequently, an increasing number of MNCs now view the initiation of international multi-center clinical trials (MRCTs) as a prerequisite for negotiation.

Health economic evidence: In European markets, whether a drug can pass a Health Technology Assessment (HTA) and gain entry into the health insurance reimbursement system is almost as important as its clinical efficacy. Chinese pharmaceutical firms that proactively arrange for health economic evidence will secure a significant premium during licensing negotiations in Europe.

> *Quotes of experienced buyer*
>
> Recent cases demonstrate that the primary reasons for MNCs handing back deals include scientific issues (such as efficacy failing to meet expectations), strategic realignments within the MNC (such as narrowing focus to core therapeutic areas), and disputes over data transparency (such as Chinese clinical data being biased toward positive results).
>
> — Scientific project manager at an MNC

2.4 A clear patient value proposition

Regulatory approval pathways and commercialization strategies ultimately rely on a clear patient value proposition regarding patient reach, the clinical needs it addresses, and the incremental value the therapy provides compared to the current standard of care. This proposition must be integrated into the design logic during the early stages of an asset's development, rather than being appended just before licensing negotiations.

3 Target market selection

The choice of destination for international expansion is a strategic decision involving the allocation of resources, capabilities, and risk tolerance. It requires a multi-dimensional assessment based on product characteristics, corporate capabilities, and strategic objectives.

3.1 European and US markets: The high-reward, high-entry-barrier battleground

Europe and the US are the major markets for innovative drugs and serve as the primary stage for maximizing the value of Chinese outbound assets. MNCs largely base their license-in decisions on the commercialization potential of the US market, using it as a pricing anchor. For Chinese innovative pharmaceutical firms, the ability to enter the US largely dictates the ceiling of their global commercial value. Venturing into the US market also necessitates meeting the local stringent requirements for clinical data quality, CMC compliance, and supply chain traceability.

3.2 Emerging markets and the Belt and Road strategic layout: Rapid access and high-potential hinterlands

Simultaneously, emerging markets—including those along China's Belt and Road initiative, Southeast Asia, the Middle East, Latin America, and Africa—are becoming strategic frontiers for an increasing number of Chinese pharmaceutical companies. In addition to relatively shorter regulatory access cycles, in these geographies Chinese firms can avail their natural competitive advantages in areas such as product cost-effectiveness and localized service capabilities. Several Chinese developers (such as Fosun Pharma, Luye Pharma, and China Medical System) have already established quite mature registration and commercialization systems within these emerging economies.

For the majority of Chinese biotechs, a dual-track strategy—comprising out-licensing to MNCs to enter Western markets alongside independent expansion or regional licensing into emerging markets—represents the optimal solution under resource constraints. The critical factor is that, regardless of the chosen path, product data must meet high international standards. This is because regulatory fast-track pathways in emerging markets are increasingly becoming contingent upon prior EMA or FDA approval.

Table 4. Comparison of global market entry strategies

	Europe/US markets	Emerging markets (Belt and Road, SE Asia, Middle East, Latin America, etc.)
Market characteristics	Global hubs for innovative drugs; the pricing cornerstone for MNCs	Relatively flexible regulatory environments; cost-effectiveness advantages
Resource requirements	Extremely high	Moderate
Return ceiling	Extremely high (market size for a single indication is several times that of China)	Moderate (capacity of individual markets is limited)
Advantages	Strong payer ability; massive market capacity; strong academic leadership; FDA approval provides global endorsement value	Rapid access; superior competitive positioning; ease of leveraging localization advantages; value as a strategic springboard
Challenges	High regulatory barriers; massive commercialization costs; geopolitical risks	Immature payment systems; poor manufacturing and supply chain infrastructure; compliance challenges
Strategic value	Brand building; high international pricing	Rapid revenue generation; accumulation of international experience; synergy with China's Belt and Road initiative
Applicable products	FIC/BIC breakthrough therapies	Approved mature products; biosimilars; incrementally modified drugs (IMDs)
Applicable companies	Large pharmaceutical firms with ample capital and dedicated teams	Small-to-medium enterprises with limited resources needing rapid validation of international capabilities

4 Main considerations of the transacting parties

International licensing negotiations unfold as a two-way value game played under conditions of information asymmetry. If the seller fails to profoundly understand the buyer's decision-making logic, they will be unable to design an attractive transaction structure.

Companies must assign different weightings to these objectives based on their specific stage of development and incorporate reasonable contractual protection mechanisms within the negotiation terms to safeguard their strategic interests.

4.1 Objectives of the Chinese seller

	Primary concern	Negotiation logic
Financial return	Upfront payment size; timing of near-term milestones	Immediate improvement of financial position and reduction of execution risk; influences capital market valuation and the corporate narrative
Long-term gains	Sales royalty rates	Ensures long-term value capture and prevents the undervaluation of core assets
Retention of control	Participation rights in clinical development decisions; retained rights for China or specific regions	Protects interests and prevents the asset from being shelved
Intellectual property	Clear ownership of underlying IP	Protects the long-term value of the platform technology
Strategic value	International endorsement and enhancement of product value	Focuses on the partner's industry influence and development capabilities

4.2 Concerns of the buyer side (MNCs/international pharmaceutical firms)

	Specific requirements	Underlying logic
Asset potential	Market size; level of innovation; competitive landscape; patent life	Determines return on investment (ROI)
Clinical data quality	Data integrity, reliability, and global acceptability	Determines probability of regulatory success
Seller team capability	Profound understanding of the project's scientific logic; execution capability; willingness to cooperate; cultural compatibility	Determines whether the project can proceed smoothly
Intellectual property clarity	Freedom to Operate (FTO); completeness of patent families	Determines commercialization risks
CMC/ manufacturing compliance	Process stability; quality system compliance; supply chain resilience	Determines risks related to regulatory approval and supply security
Geopolitical and supply chain risk	Whether the transaction is subject to Committee on Foreign Investment in the US (CFIUS) review; export controls	Determines whether the deal can be approved

4.3 The licensing logic of MNC buyers

MNC BD teams operate in an environment of intensifying competition for assets and internal capital allocation pressures. Their primary motivations for acquiring Chinese assets can be categorized as follows:

Pipeline supplementation: The pressure of the patent cliff forces MNCs to continuously seek new growth drivers.

Technology platform acquisition: Some MNCs focus not only on individual assets but also aim to acquire or partner with Chinese firms to gain access to their foundational technology platforms.

R&D efficiency advantages: Chinese biotechs demonstrate remarkable R&D efficiency. Within a given stage, the pace of Chinese development is faster than in Europe or the US, while costs are typically only 30% to 50% of Western counterparts.

Asset cost-effectiveness: Compared to internal R&D costs—which often exceed USD 2 billion per drug—in-licensing assets from China offers significant economic advantages, even when substantial milestone payments are involved.

Regional strategy: MNCs with deep roots in the Chinese market leverage partnerships to simultaneously facilitate easier market access within China.

Key takeaway: The certainty premium

A Chinese pharmaceutical firm with the ability to demonstrate that its clinical data was collected by a global compliance-native Contract Research Organization (CRO), its manufacturing processes were executed by a Contract Development and Manufacturing Organization (CDMO) that has passed EMA or FDA on-site inspections, and its supply chain possesses a traceable quality record system, will negotiate consistently higher valuations relative to competitors lacking such endorsements.

Certainty has become a highly valuable intangible asset in current international expansion negotiations.

5 Partner screening and selection

Choosing the right partner is a critical strategic decision that determines the success or failure of international expansion. Selecting the wrong partner can lead to missed milestones and deprioritization; it may even result in the asset being shelved due to the partner's internal strategic shifts.

5.1 Partner profiling

	Advantages	Disadvantages	Applicable scenario
Global MNCs	Powerful commercialization networks; extensive registration experience; strong brand endorsement	Long decision-making chains; risk of assets being shelved; significant disparity in bargaining power	High-value assets requiring global commercialization capabilities
Regional pharmas	Flexible and efficient; deep roots in specific regions; strong motivation	Limited global coverage; relatively weaker financial strength	Regional licensing; deep penetration into specific markets
Platform/ special purpose companies (NewCo)	Capital-driven; clear incentive mechanisms; rapid decision-making	Unverified commercialization capabilities; risks regarding capital chains	Phase II or earlier-stage assets requiring independent overseas incubation
Mid-sized biopharma	Clear ownership of underlying IP	Protects the long-term value of the platform technology	Out-licensing of specific indications

5.2 Partner evaluation framework

The screening of high-quality partners should be based on the assessment of the following key factors:

1. **Strategic fit:** The level of priority the asset holds within the partner's internal pipeline.
2. **Domain expertise:** Relevant clinical and regulatory experience within the specific therapeutic area.
3. **Transaction track record:** Evidence of past conduct, specifically whether there is a precedent for unilaterally shelving licensed assets due to changes in strategy.
4. **Commercialization capability:** The scale of the sales force and the strength of pricing and reimbursement negotiation capabilities in target markets.
5. **Decision-making and execution efficiency:** Considering that decision cycles for large MNCs can span 12 to 18 months, whereas mid-sized companies may require only 3 to 6 months.
6. **Financial robustness:** The overall fiscal health and funding stability of the organization.
7. **Cultural compatibility:** The alignment of corporate values and communication styles.

6 Deal structure design and execution safeguards

Even with high-quality assets and the right partner, deal terms will largely determine the extent of value realization. A well-designed transaction must anticipate and mitigate execution risks from the outset.

6.1 Comparison of mainstream deal model structures

Asset licensing: The predominant model, where the seller grants the buyer the rights to develop and commercialize a product within specific geographies in exchange for an upfront payment, milestone payments, and sales royalties. Key terms include the scope of the license, territory, financial terms, IP ownership, the authority and decision-making mechanisms **of the Joint Development Committee (JDC), allocation of supply chain responsibilities, and termination clauses.**

Co-development: Both parties commit resources (capital, personnel, and technology) to develop the asset, sharing both risks and rewards. This model demands highly sophisticated design regarding cost-sharing ratios, the division of JDC authority, and deadlock resolution mechanisms. It requires detailed agreements on the scope of work, resource commitment, and future profit-sharing models post-commercialization. Decision-making is typically managed through joint committees, where defining roles for execution versus final approval is critical.

NewCo: Assets are injected into a newly established special-purpose entity, attracting external capital to realize value through an independent IPO or M&A. While this model offers high flexibility, it carries significant complexity of designing IP ownership, control arrangements, and exit mechanisms, requiring involvement from top-tier legal and investment banking teams. **Advantages** include:

1. Achieving higher valuations and deeper capital integration;
2. Mitigating geopolitical risks by housing assets within a pure offshore entity;
3. Leveraging professional funds to empower corporate governance and subsequent financing rounds.

The lifeblood of a deal lies in its terms. Safeguards should be established regarding exclusivity scope, decision-making mechanisms, the frequency of information and data sharing, termination and reversion clauses, and IP ownership.

Table 5. Comparison between the three major deal models

	Licensing	Co-development	NewCo
Applicable scenario	Seller lacks overseas development and commercialization capabilities	Seller wishes to retain greater control and potential returns	Early-stage assets intended to capture capital premiums through an independent entity
Key terms and clauses	Scope of license and territorial definitions; obligations (binding development timelines); data ownership upon termination	JDC mechanism (unanimous consent vs. lead party); allocation of supply chain responsibilities; budgetary control; IP ownership	Equity ratio and voting rights for the originator; board seats and veto rights; exit mechanisms (IPO/M&A priority)
Main risks	Partner slows development due to strategic shifts; asset is shelved	Low decision-making efficiency; disagreements over clinical trial design	Dependence on continuous financing; stagnation if capital markets cool down; high operational complexity and long cycles
Representative cases	Biokin-BMS	Innovent-Takeda	Hengrui-Kailera (Retained 19.9% equity)

Quotes of experienced seller

The choice of deal model is tied to the company's own scale and the importance of the product. The larger the platform and the more essential the product, the more a company will lean toward complex collaboration models, as these represent greater potential returns.

— Senior BD Manager at a leading biopharma

6.2 Ensuring execution: Embedding certainty within the agreement

A critical, yet often overlooked, principle is that safeguards for transaction execution must be considered during the agreement design stage, rather than attempting to mend the situation after a dispute has arisen. The following factors are particularly important:

Clear allocation of rights and responsibilities in clinical development:

- Composition, decision-making mechanisms, and dispute resolution procedures of the JDC
- Clinical trial design
- Selection and management of **Contract Research Organizations (CROs)**
- Approval processes for amendments to clinical protocols
- Ownership of data
- Timelines for key milestones and the consequences of default
- Adjudication mechanisms for disagreements during cross-reviews

Explicit definition of supply chain responsibilities: Ambiguity within the supply chain is one of the most frequent points of conflict in international collaborative projects.

- Manufacturing and release of clinical trial material (CTM)
- Quality standards, delivery schedules, and approval mechanisms for clinical supply
- Standards, timing, and acceptance criteria for technology transfer
- Commercial manufacturing arrangements: Whether to use in-house capacity or outsource to a CDMO
- **Contingency plans for supply chain disruptions:** Identifying the party responsible for the qualification of alternative suppliers, and the mechanism for assigning liability for clinical delays caused by supply chain breaks

Commercial constraints: In out-licensing transactions, insufficient commercial investment by the buyer is a risk that frequently leads to the product value not being fully realized.

- Minimum commercial investment
- **Submission frequency of sales plans and KPIs Protective mechanisms for the seller upon underperformance** (such as the conditions for triggering termination rights)

Dynamic allocation of IP: Clear definition of IP ownership rules is essential for protecting the long-term value of platform technologies.

- Definition and scope of use for background IP
- Ownership and licensing of foreground IP
- Responsibility for third-party **infringement litigation** Information transparency
- Frequency and content requirements for development progress reports
- Sharing of communication records with regulatory authorities
- Timeliness of adverse event reporting

A significant number of international licensing deals fail not during the negotiation phase, **but during the execution phase, typically 6 to 18 months after the partnership begins. High-standard CROs, CDMOs,** clinical supply chain providers, and bioprocessing raw material suppliers are critical in mitigating breach-of-contract risks and ensuring clinical data is recognized by global regulatory bodies. Selecting the right service providers constitutes a vital risk buffer that exists beyond the written contract.

> *Quotes of experienced seller*
>
> Because a formal manufacturing and supply agreement was not signed, the partner prioritized supply for the US market, leading to delays in the recruitment of Chinese patients... Furthermore, as the contract did not explicitly define the scope of data sharing, our company was ultimately only able to access the data the partner was willing to disclose.
>
> — Business operations director at a biotech

7 Efficient process management

In the practice of international BD, process management is often viewed as a secondary task, leading to a severe undervaluation of its strategic importance. In reality, for the BD teams of MNCs, the level of professionalism and the process management capabilities demonstrated by a Chinese counterpart are essential factors in assessing their overall competence. Sluggish response times, incomplete data packages, and ambiguous IP documentation can trigger doubts within the buyer's internal team regarding the seller's execution capabilities, which in turn adversely affects valuations and deal terms.

The full cycle of an international transaction typically comprises:

1. Initial preparation: 1–3 months
2. Preliminary contact and intent evaluation: 2–4 months
3. NDA/CDA execution and initial assessment: 1–2 months
4. Term sheet negotiation: 1–3 months
5. Technical and BD due diligence: 2–6 months
6. Definitive agreement negotiation and signing: 2–4 months
7. Closing and transaction effective date

Due diligence and the preparation of a data room are the key stages for eliminating information asymmetry. Sellers should establish a clearly structured virtual data room (VDR)—containing legal documentation, financial records, R&D data, CMC materials, and compliance records. The completeness and professionalism of the data room serve as a direct reflection of a company's management standards. In practice, many Chinese pharmaceutical firms lack standardized data room management systems; data sharing mechanisms often operate independently across subsidiaries or business units without unified group-level oversight, which frequently creates an efficiency bottleneck when launching external collaborations. Furthermore, in practice, the rhythm and boundaries of information disclosure are critical factors for negotiation and leverage, rather than a one-time full disclosure.

Every partnership has a specific window of opportunity; once missed, the loss is often irreparable. This imposes two requirements on an organization: first, the BD team must achieve internal alignment before reaching critical milestones; and second, the management team must recognize that procedural efficiency is itself a competitive advantage, as excessively long decision-making chains can lead to the loss of collaboration opportunities.

8 Strategic planning for overseas regulatory registration

Overseas registration requires proactive planning and dynamic adjustment. Selecting the correct regulatory pathway can secure a competitive time advantage of 1 to 3 years for a product. From the perspective of international valuation logic, overseas registration—specifically US FDA filings—is an effective means of enhancing an asset's outbound value. Even if a company does not intend to enter the US market independently in the short term, completing an FDA filing commands a significant premium in valuations by MNCs.

8.1 FDA expedited approval pathways

The FDA has established several expedited pathways for innovative therapies that address significant unmet medical needs. Chinese pharmaceutical companies should systematically evaluate the applicability of these pathways during the early stages of clinical design.

Table 6. FDA approval pathways

	Eligibility criteria	Key benefits	Applicability to Chinese firms
Breakthrough therapy designation (BTD)	Drugs for serious or life-threatening diseases where preliminary clinical evidence indicates significant improvement over existing therapies	Intensive FDA guidance, rolling submission, and expedited review	Half of the China-originated products approved in the US have received FDA BTD status
Fast track (FT)	Treatment of serious conditions that fill an unmet medical need	Rolling submissions and more frequent communication with the FDA	Broadly applicable; Chinese firms have a high success rate in these applications
Accelerated approval (AA)	Based on a surrogate endpoint or an intermediate clinical endpoint	Approval based on surrogate endpoints, subject to confirmatory trials	Suitable for indications with clearly defined efficacy markers
Priority review (PR)	Treatment for serious conditions offering significant improvements in safety or efficacy	Review cycle shortened from 10 months to 6 months	Most BTD and FT drugs receive also PR

8.2 EMA PRIME scheme and European regulatory strategy

The EMA Priority Medicines (PRIME) scheme is specifically designed to provide early, enhanced support for drugs that can address unmet medical needs. Benefits include scientific advisory resources and eligibility for accelerated assessment. Given the low success rate of Chinese pharmaceutical companies applying for PRIME, it is recommended that a comprehensive pre-assessment be conducted via top-tier European regulatory consultancy teams prior to application.

Table 7. EMA approval pathways

	Eligibility criteria	Key benefits
PRIME	Treatments with significant therapeutic potential for serious conditions, based on early-stage data	Early interaction, accelerated review, and early appointment of a rapporteur
Accelerated assessment	Treatment of serious conditions; major public health interest	Review period shortened from 210 days to 150 days
Conditional marketing authorization (CMA)	Unmet medical needs where benefits outweigh risks and complete data is expected to be generated	Approval based on incomplete data, subject to the completion of post-marketing studies

8.3 Regulatory pathway strategies based on MRCTs and bridging studies

For assets that already possess comprehensive clinical data from Chinese populations, the core challenge during FDA or EMA registration lies in the possibility of extrapolating that data. There are two main routes to address this:

Bridging studies: This route is primarily suitable for assets that have completed significant clinical development in China and seek to support an overseas marketing application by combining Chinese data with supplementary studies (bridging trials) conducted in regions such as the US. This pathway is particularly suitable for orphan drugs or breakthrough therapies targeting unmet clinical needs. The challenge lies in providing a robust justification for the applicability of Chinese population data to external populations such as US patients.

MRCTs: By conducting registrational trials simultaneously across multiple countries, the global acceptability of the data is significantly strengthened. This is the **ideal registration pathway** for Chinese innovative drug companies going global. However, the prerequisite is that the trial must meet high global standards from the design phase onwards. Any weakness in the chain—be it data management, statistical analysis, or the quality of clinical supply—could lead the FDA to question the integrity of the entire data package during review. An increasing number of Chinese firms are choosing to initiate MRCTs at the Phase III stage to maximize efficiency through a one-trial global registration approach.

From the perspective of frontline practitioners, overseas registration (particularly FDA filing) plays a strategic role in the global value chain that transcends mere regulatory compliance. **For novel drugs with high-value targets, securing overseas registration is the primary route for validating their innovative attributes.** Nevertheless, a rational approach is required: blindly pursuing overseas registration solely for the innovation label—without a rationale for commercial returns—may result in excessive costs that ultimately hinder the overall corporate strategy.

9 Overseas clinical development strategy and execution

Whether pursuing independent or collaborative international expansion models, clinical development represents a high-investment, high-risk phase. A successful transaction is merely the beginning; the true test lies in whether development can proceed according to plan post-signing and whether the resulting data will be recognized by global regulatory authorities.

Clinical development strategies for independent expansion: This approach is suitable for well-capitalized companies that have already established international clinical teams (such as BeOne). The main objective is to build globally integrated **clinical operational capabilities.** Strategies include:

1. Global synchronized development planning from the early stages (e.g., conducting Phase I trials simultaneously in Australia, China, and the US).
2. Building or hiring clinical development teams with multi-regional regulatory experience.
3. Adopting a model of global coordination coupled with local execution for CROs.

Clinical development strategies for collaborative expansion: Under out-licensing or co-development models, defining the roles and responsibilities of each party within clinical development is critical. It is recommended to manage this using the logical framework of **the Transaction model × clinical governance RACI matrix.**

9.1 Transaction model × clinical governance RACI matrix

Fundamentally different roles and responsibilities exist for each party across various transaction models. The following RACI framework (Responsible, Accountable, Consulted, Informed) provides a reference for Chinese pharmaceutical companies during the agreement design stage:

Clinical governance	Out-licensing	Co-development	NewCo
Seller	Accountable: • Responsible for China-region CRO selection and clinical operations • Safety monitoring and data ownership in China Responsible: • Provide Chinese clinical & non-clinical data for regulatory filings Consulted: • provide China-specific early-stage trial design and data into global clinical protocol design Informed: Global clinical development	Accountable: • Joint safety monitoring and shared data ownership Responsible: • Subject to JDC approval, align on global clinical strategy, protocol design, and CRO selection • China-region clinical trials • Provide support for regulatory submissions	Responsible: • Execute China-region clinical trials • Provide historical data for regulatory filings Consulted: • Early-stage clinical trial protocol design Informed: Global clinical strategy, mid-to-late-stage clinical design, CRO selection, and safety monitoring
Buyer /NewCo	Accountable: • Responsible for global clinical strategy, protocol design, and global CRO selection • Ex-China regulatory filings • Global safety monitoring and ownership of global data Informed: China-region clinical execution	Accountable: • Regulatory filings and shared data ownership Responsible: • Subject to JDC approval, align on global clinical strategy, protocol design, and CRO selection Consulted: Oversight of China-region clinical trials	Accountable: • Responsible for global clinical strategy, protocol design, and CRO selection • China-region clinical trials • Ex-China regulatory filings Global clinical strategy, mid-to-late-stage clinical design, CRO selection, and safety monitoring

JDC: Joint Development Committee

The clarification of this framework prior to the signing of the agreement is key to avoid execution conflicts later on. Under a co-development model, decision-making authority regarding clinical development is prone to divergence. The design of the JDC's decision-making process—particularly the deadlock-breaking mechanism—must be explicitly agreed upon at the time of signing, lest subsequent development should descend into endless internal maneuvering.

9.2 The strategic positioning of CROs: From cost-outsourcing to strategic symbiosis

The choice of a CRO directly determines whether clinical data will be recognized by stringent global regulatory bodies such as the FDA and EMA. In international clinical development, the overriding principle for CRO selection is that the data must **be flawless under global regulatory scrutiny.**

Selection criteria should focus on:

International project experience: Whether they possess experience managing global MRCTs under FDA/EMA oversight, whether past projects have passed regulatory audits, and their ability to coordinate centers across the US, Europe, and Asia-Pacific to meet the data requirements of different regulatory agencies.

Quality management system (QMS): Whether they have established a quality system audited and approved by the FDA or EMA, and whether they have recently passed regulatory on-site inspections without major deficiency records.

Data compliance and technical capability: Whether electronic data capture (EDC) systems comply with 21 CFR Part 11, and whether biostatistical analysis resources meet international guidelines such as ICH E9, alongside robust guarantees for data integrity.

Cross-regional communication and project management: The maturity of the CRO's cross-regional communication and project management, which directly impacts execution efficiency and conflict resolution speed when coordinating between Chinese sponsors, Western buyers, and multinational investigators.

Therapeutic area expertise: Sufficient project experience in the target indication, as well as a strong patient recruitment network and key opinion leader (KOL) resources.

Service pricing: The ability to provide competitive pricing, which remains a key focus for Chinese enterprises.

Previous collaboration experience: Selecting a CRO with a proven track record of partnerships, which can significantly reduce ineffective communication costs and the risk of eventualities.

A profound strategic shift is currently transforming the partnership model between Chinese drug developers and CROs:

Global top-tier CRO partners are being repositioned from cost-center vendors to strategic components of a virtual R&D center. This means that Chinese firms are no longer seeking CROs only after a transaction is completed; instead, they are engaging global compliance-native R&D service partners during the early stages of asset development. These partners participate in trial design, data strategy, and regulatory communication, thereby building the execution credibility that global buyers value so highly. CROs with global compliance credentials and excellent FDA audit records are becoming an irreplaceable quality endorsement for international projects.

10 Overseas manufacturing and supply chain infrastructure

A stable, reliable supply chain that adheres to international standards is the fundamental guarantee of drug accessibility and the lifeline of both regulatory approval and commercial success. Historical data and regulatory practice have repeatedly demonstrated that **a significant proportion of international expansion projects ultimately fail not due to inadequate clinical data, but because manufacturing processes and supply chains fall short during regulatory inspections.**

In July 2025, the FDA for the first time publicly released 202 Complete Response Letters (CRLs) issued between 2020 and 2024, which included four Chinese innovative drugs. **Chemistry, manufacturing, and controls (CMC) issues remain one of the most frequent reasons for the rejection of Chinese innovative medicines during the FDA review process.**

Table 8. CMC compliance warning cases

Company	Drug	CMC-related issues
Generic pharmaceutical firm	Vancomycin hydrochloride injection	Manufacturing facility violations
Pharmaceutical firm	Risperidone injection	Dose dumping risks (manufacturing process issues)
Innovative biotech	Bevacizumab biosimilar	Microbiology and manufacturing process controls deficiencies
Innovative biopharma	Monoclonal antibody (unspecified)	Unstable master cell banks

Overseas supply chain infrastructure strategies for independent global expansion: For companies planning independent commercialization overseas, supply chain layout must be established several years in advance.

Strategies include:

1) Building or acquiring current good manufacturing practice (cGMP)-compliant production bases near target markets (e.g. Europe or the US).
2) Establishing strategic collaborations with CDMOs that possess global capacity networks to ensure production redundancy.
3) Building a global supply chain management team responsible for the end-to-end chain, from Regulatory Starting Materials (RSM) to finished product distribution.

The key for building an overseas manufacturing system is not merely finding a supplier capable of production, but rather selecting a platform-based partner capable of covering process development, analytical method establishment, clinical sample production, technology transfer, process performance qualification (PPQ), and commercial scale-up. The value of such partners lies in minimizing technical transfer gaps between development and launch, thereby enhancing CMC consistency and global filing efficiency. Using a service system like Thermo Fisher Scientific's pharma services model as an example, the significance lies in converting manufacturing capacity into a sustainable delivery capability within global regulatory frameworks.

Overseas supply chain infrastructure strategies for collaborative global expansion: Under out-licensing or co-development models, supply chain responsibilities are typically clearly partitioned within the agreement. The requirements for supply chain control and information transparency across different transaction models can be analyzed using the following transaction model × supply chain control matrix.

10.1 Transaction model × supply chain control RACI matrix

Systematic differences exist regarding the demands for supply chain control and information transparency between buyers and sellers under different transaction models:

Supply Chain	Out-licensing	Co-development	NewCo
Seller	Responsible: • Clinical supply prior to tech transfer • Technology transfer • Provision of historical CMC compliance data Informed: • Commercial manufacturing, vendors, and quality audits	Accountable: • Responsible for Commercial manufacturing within respective territories • Mutual audits; shared supply chain risks and compliance liabilities Responsible: • Subject to JDC approval, jointly execute clinical supply and vendor selection • Technology transfer	Responsible: • Clinical supply prior to tech transfer • Technology transfer • Provision of historical CMC compliance data Informed: Commercial manufacturing, vendors, and quality audits
Buyer /NewCo	Accountable: • Clinical supply, commercial production, vendor selection, quality audits, and tech transfer • Assume supply chain continuity risks and CMC compliance responsibilities	Accountable: • Commercial manufacturing and tech transfer within respective territories • Cross-auditing; joint responsibility for supply chain continuity and compliance Responsible: • Subject to JDC approval, align on management of clinical supply and vendor selection	Accountable: • Clinical supply, quality audits, and tech transfer • Assume supply chain continuity risks and CMC compliance responsibilities • Responsible commercial manufacturing and vendor selection

Key risk alerts:

- In an **out-licensing model**, supply chain risk is primarily assumed by the buyer once technology transfer is complete; however, the seller must ensure the integrity and reproducibility of said transfer. A common issue arises when the seller's CDMO fails the buyer's quality audit, leading to technology transfer delays of months or even years.
- Under a **co-development model**, supply chain control is a frequent area of dispute. At the time of signing, the partners must explicitly agree on which party selects the CDMO, which party bears quality responsibility, and how changes to clinical supply are approved.
- In a **NewCo model**, the NewCo possesses greater autonomy over the supply chain but also faces more severe challenges. As a newly established entity, it often lacks supply chain management experience and must rely heavily on CDMO partners.

10.2 CDMO selection criteria: From "capable" to "globally trusted"

During the review of the CMC module (Module 3) of an FDA New Drug Application (NDA), three categories of issues frequently lead to review delays or failure: **insufficient process reproducibility** (inability to prove consistency between commercial and clinical batches), **deficiencies in analytical method validation** (methods not fully validated or incomplete transfer records), and **poor regulatory compliance of starting materials** (the FDA's traceability requirements for specific animal-derived or human-derived materials are becoming increasingly stringent).

Selecting a CDMO and supply chain partners is not a simple procurement decision, but a strategic choice upon which the success of international expansion hinges. A CDMO's quality system, compliance record, and global reputation directly determine whether the CMC section of an FDA review will pass smoothly, as well as the buyer's confidence in the asset's potential during due diligence. Consequently, the essence of CDMO screening is not a comparison of price or capacity, but an assessment of its ability to provide cross-stage integration, global quality systems, regulatory support, and multi-regional supply capabilities.

Five key selection criteria:

1. Quality system compliance with international GMP standards, such as those of FDA/EMA:

- Have the provider's facilities passed audits by regulatory bodies such as the FDA, EMA, or PMDA?
- Does the QMS cover the entire chain from raw materials to finished products?

2. Stable global supply network and flexible capacity:

- Do they have a multi-regional capacity layout (e.g. a China + West dual-hub model)?
- Does raw material procurement include multi-source backup capabilities?
- Do logistics partners possess global cold-chain management experience?

3. Resilience planning for geopolitical risks:

- Have they formulated supply chain de-risking solutions?
- Are there capacity transfer contingency plans for extreme scenarios such as export controls or sanctions?
- Do they possess supply chain backup plans?

4. Excellent regulatory reputation and proven track record:

- How have they performed in historical FDA/EMA audits?
- Do they have experience in providing commercial manufacturing for marketed drugs?

5. End-to-end service capabilities:

- Can they provide one-stop services ranging from process development to commercial manufacturing?
- Can they support the drafting of regulatory filing documents and responses to review queries?

From a practical standpoint, platform-based CDMOs capable of simultaneously covering development, clinical studies, regulatory support, commercial scale-up, and global supply networks are more likely to become long-term partners for Chinese pharmaceutical companies during their international expansion. Service systems exemplified by Thermo Fisher Scientific's pharma services model are better suited for projects requiring cross-stage integration and global registration.

The professional management of the clinical supply chain is a key execution element that is often overlooked. The clinical supply chain is not merely simple logistics management; it is an execution system that connects CMC, clinical operations, and regional regulatory requirements. The manufacturing, packaging, labeling, release, storage, temperature-controlled transport, and global distribution of investigational medicinal products must be designed in coordination with the trial protocol, recruitment speed, and compliance requirements of each region. Platform partners with clinical supply service capabilities can mitigate recruitment delays and trial risks caused by supply interruptions, labeling errors, or release delays.

Certainty: The key barrier to succeeding internationally

The global expansion of Chinese innovative drugs has entered a critical stage of development, where success no longer relies on isolated breakthroughs but on systematic capacity building. Enterprises must define their international objectives at a strategic level, develop products with global competitiveness, and select target markets and partners accordingly. During transaction execution, uncertainty is converted into certainty through professional process management, ingenious registration strategies, efficient clinical development execution, and the construction of a solid global supply chain system.

The key to succeeding abroad lies in achieving high levels of certainty. This certainty must permeate every link from product discovery to global commercialization: the scientific advantages of a product provide "clinical certainty"; the selection of appropriate target markets and partners provides "commercialization certainty"; ideal transaction models and professional process management provide "transaction certainty"; the global compliance of CROs provides "data certainty"; the international GMP quality systems of CDMOs provide "CMC certainty"; and the multi-regional resilience of the supply chain provides "supply certainty".

The International Expansion Certainty Value Chain

Scientific advantages and differentiated competitiveness of the product → **Clinical development certainty**

Selection of appropriate target markets and partners → **Commercialization certainty**

Ideal transaction models and professional process management → **Transaction certainty**

Support from global compliance-native CROs → **Data certainty**

Guarantees from CDMOs that have passed international GMP audits → **CMC certainty**

Supply chain systems with geopolitical resilience → **Supply certainty**

From strategy planning to ground-level execution, and from product competitiveness to supply chain resilience, the construction of certainty at every stage ultimately converges toward the path to international success. In this process, deep collaboration—or even the formation of strategic alliances—with high-standard R&D and manufacturing service providers, such as CROs and CDMOs, to jointly build quality and delivery systems capable of withstanding global regulatory and market scrutiny is a vital guarantee for Chinese innovative pharmaceutical companies to navigate industry cycles and achieve global success.

04

Overcoming geopolitical and regulatory barriers: Global risk management

The preceding sections have detailed strategies for building high levels of certainty in international expansion. In practice, however, even firms that systematically develop these capabilities may still face shocks from external risks such as geopolitics, regulatory discrepancies, and changes in partnership dynamics. Through policy adjustments like Project Optimus and guidelines on clinical trial population diversity, the FDA has significantly raised the requirements for clinical development quality and global representativeness.

In this chapter, we will systematically review the key challenges and response strategies faced by Chinese pharmaceutical companies going abroad. By synthesizing these experiences, we aim to provide a valuable strategic reference for the next stage of higher-quality, more successful, and sustainable international expansion for Chinese innovative medicines.

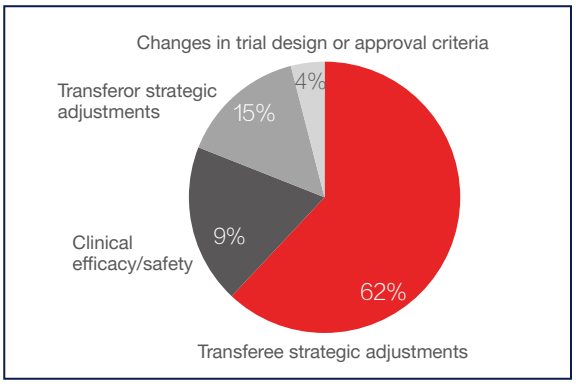
1 Obstacles and causes of failure in international expansion

In recent years, as the R&D capabilities of Chinese innovative drugs have grown, license-out transactions—a vital component of international expansion—have become a key route for Chinese firms to gain international recognition and maximize value. However, not all transactions proceed smoothly to success. Data from 2014 to 2025 shows that (Figure 11) the number of terminated Chinese license-out deals has fluctuated upwards, peaking at 10 terminations in 2024 before receding to 3 in 2025. This indicates that, behind the booming transaction activity, termination risks driven by the capital environment, competitive landscape, and regulatory requirements cannot be ignored.

Figure 11. Yearly amount of terminated Chinese license-out transactions between 2014 and 2025

Data source: PharmCube's NextBiopharm database.
Notes: Data includes transactions involving innovative drugs and technology platforms only, excluding traditional Chinese medicines, preventive vaccines, generics, modified new drugs, and biosimilars. Data cutoff date is December 31, 2025.

Figure 12. Reasons for transaction termination



Data source: PharmCube's NextBiopharm database.
Notes: Reasons for termination are derived from public statements.

A comprehensive analysis of terminated Chinese license-out transactions reveals that the primary causes (Figure 12) can be categorized into the following areas:

- **Transferee strategic adjustments (62%):** This is the most common reason for barriers or failures in international expansion, further subdivided into:
  1. **Portfolio and strategic realignment:** The asset faces intense competition and has fallen behind in the competitive landscape.
  2. **Transferee organizational changes:** Following the licensing, the asset no longer aligns with the acquirer's strategy, or the pipeline cannot progress due to the transferee's bankruptcy or insufficient funding.
- **Clinical efficacy/safety (19%):** When the efficacy or safety performance of the incorporated asset or same-target competitors is poor, the risks associated with further development are substantial, potentially leading to failure or the return of rights
- **Transferor strategic adjustments (15%):** The transferor reclaims previously transferred commercialization rights to sell the product directly
- **Changes in trial design or approval criteria (4%):** The clinical trial protocol design—including the selection of participants, control groups, and endpoints—fails to meet the requirements of overseas regulatory authorities

It is noteworthy that beyond the termination of license-out deals, obstacles to the global expansion of Chinese innovative drugs also include independent expansion failure (where a pharmaceutical company independently pushes a product into overseas markets but faces a low probability of commercialization or total failure) and the receipt of a CRL (where an application is not approved, requiring supplementary data or the resolution of manufacturing quality issues). A CRL does not necessarily represent total failure; many Chinese firms successfully launch products after providing supplementary materials. Hence, such setbacks should be viewed instead as opportunities for strategic adjustment.

Case 1.

A Chinese innovative drug receives CRLs for solid tumor indication: The importance of CMC compliance for international expansion

The overseas partner for this drug submitted a New Drug Application (NDA) to the FDA for the first-line treatment of a specific advanced solid tumor indication. However, the launch process encountered setbacks after receiving CRLs. The documents primarily involved deficiencies in manufacturing site inspections, compliance rectification, and supplementary responses. Following extensive remediation and ongoing communication, the overseas partner resubmitted the application, with the expected launch date for this drug now significantly delayed.

Key takeaway: The key to global approval for innovative drugs is not limited to clinical data; CMC compliance and manufacturing quality systems have become pivotal. International GMP standards and CMC compliance must be established during early-stage R&D to improve global filing success rates.

Case 2.

Small-molecule innovative drug: Supplementing Chinese data with a bridging study is no longer viable

This innovative drug targets a specific advanced solid tumor indication. Based on data from two successful Phase III studies conducted in China, the molecule was approved for marketing in the country. To enter the US market, the Chinese firm adopted a "Chinese data + US bridging" strategy and completed a Phase Ib bridging trial in the US.

However, the FDA issued a CRL, rejecting its marketing application. The letter explicitly stated that the positive data from the two Chinese late-stage studies and one US bridging trial were insufficient to support approval, and that a MRCT including a more representative US patient population was required. Following the receipt of the CRL, the Chinese firm voluntarily withdrew its NDA filing in the US.

Notably, prior to submitting the NDA, the Chinese firm communicated with the regulatory authorities and believed the existing Chinese Phase III and US bridging data could constitute a valid basis for submission. However, the final review concluded the opposite, indicating that consensus on principles reached during early communication may change dynamically during the late-stage review process.

Key takeaway: The "Chinese data + US bridging" route is no longer feasible; MRCTs should be the default option for global development.

Case 3.

An ADC: Project termination due to insufficient efficacy

An overseas partner acquired the exclusive rights to develop and commercialize an ADC outside Greater China for a potential total transaction value exceeding USD 1 billion.

Years later, the overseas partner announced that the Objective Response Rate (ORR) and Disease Control Rate (DCR) results from a Phase I trial of the drug in a specific advanced solid tumor indication failed to meet company expectations. Lacking competitiveness compared to other investigational drugs targeting the same pathway, the partner decided to discontinue further development.

As a mid-sized innovative pharmaceutical company with limited resources, the overseas partner had to concentrate its funding on pipelines with a higher probability of success. When the commercial prospects for an innovative drug are unclear, terminating development to mitigate further losses is a rational business decision. This also reflects the high sensitivity of international buyers to clinical trial data and their rigorous internal strategic decision-making processes.

Key takeaway: For targets where competition is fierce, assets lacking a differentiated advantage—even if successfully licensed—remain at risk of being discontinued by the transferee due to subsequent data.

Case 4.

BsAb: Termination of cooperation due to change in transferee's strategy

This BsAb features an innovative mechanism of action. An overseas partner announced an exclusive licensing agreement for the rights to develop and commercialize the antibody in the US market. However, following a strategic realignment and a narrowed focus in oncology, the partnership for this BsAb was thus terminated and returned the rights.

Key takeaway: Strategic adjustments by the transferee are the primary reason for the termination of license-out transactions; when selecting a partner, it is essential to evaluate their strategic stability and degree of dependence on the pipeline.

2 Key challenges and response strategies for Chinese pharmaceutical companies expanding overseas

To gain a more comprehensive and objective understanding of the pain points and requirements of Chinese drug developers in their international expansion efforts, PharmCube designed a specialized survey. The primary participants were senior executives (director level and above) from Chinese pharmaceutical firms, including both biotechs and large-scale enterprises. The study focused on critical challenges encountered during the expansion process and the demand for professional services throughout the workflow. A total of 137 valid responses were collected (survey period: April 2026). The results of this survey provide a solid data foundation to analyze challenges and formulate response strategies, while offering a reference for Chinese pharmaceutical companies preparing for or undergoing international expansion.

The survey mainly covers the following two themes:

- **Demand for service provider support:**
  1) Type of support: overseas regulatory consultancy and filing support (IND, NDA); strategic and transaction advisory (expansion pathway planning, partner identification, deal negotiation); contract negotiation and legal due diligence; overseas resource matching for clinical CROs; overseas resource matching for clinical CMOs/CDMOs; market access and pricing strategy consultancy; IP due diligence and patent positioning; overseas recruitment and training; supply chain compliance; virtual data room services; support for additional financing and capital operations.
  2) Requirements: a deep understanding of the pain points faced by Chinese firms going abroad; authentic overseas resources and case studies; transparent pricing and success rate disclosures; team configurations with international backgrounds and localized service capabilities; end-to-end, one-stop service capabilities
- **Key challenges faced:** Geopolitics (China-US relations, Biosecure Act, etc.), regulatory barriers across different regions (interpretation of registration and review policies), overseas clinical trial development (protocols, CROs), overseas clinical manufacturing (CMO/CDMO), overseas supply chains, overseas commercialization, IP protection and litigation risks, overseas talent acquisition and team building.

2.1 Service provider demand

Regardless of the chosen expansion strategy, Chinese pharmaceutical companies must resort to professional service providers to bridge gaps in international experience, localized networks, and specialized capabilities. The demand for service provider support among Chinese developers is highly concentrated, revealing the main pain points of going abroad:

1. **Overseas regulatory consultancy and filing support (75.9%):** This is the critical challenge facing all pharmaceutical companies expanding internationally. Regulatory systems vary significantly across different countries and regions, and processes are complex. Chinese firms lacking local experience require professional regulatory guidance to ensure the compliance and efficiency of their R&D and registration pathways.
2. **Strategic and transaction advisory (67.9%):** International expansion is a complex commercial strategic activity. Enterprises need external expertise to plan optimal pathways, identify and screen compatible overseas partners, and receive professional support during critical deal negotiations.
3. **Contract negotiation and legal due diligence (54.7%):** Following closely behind strategy and transactions, legal support is vital. This reflects that in processes such as BD transactions and collaborative development, the rigor of contracts, risk mitigation, and legal due diligence are the cornerstones of ensuring successful cooperation and protecting one's interests.
4. **Other requirements (below 50%):** Classified as secondary requirements.

Overall, the most urgent needs for Chinese pharmaceutical companies going abroad are regulatory access, commercial strategy and transactions, and legal safeguards; these three elements constitute the fundamental framework for successful international expansion.

For service providers, the customer's focus varies depending on the stage of the company's expansion. In the early stages, enterprises require navigation (where the markets are and whether expansion is viable), while in the later stages, they require execution (how to trade and how to sign contracts).

An analysis of companies with established expansion strategies reveals that different strategies involve unique combinations of service requirements.

- **Independent expansion requires comprehensive capability support:**
  1) Strategic and transaction advisory, together with overseas regulatory consultancy and filing support, are equally prioritized (both at 69.1%); as there is no partner to share the pressure, enterprises require guidance across the entire workflow, from strategy planning to regulatory filing.
  2) The demand for overseas resource matching for clinical CROs is prominent (45.2%), which is inherent to independent expansion. Companies must conduct clinical studies overseas independently or through CROs, leading to an urgent need for high-quality overseas resource matching.
  3) Notably, this group has a relatively low demand for additional financing and capital operations support (7.1%), suggesting that companies choosing independent expansion typically possess stronger finances and a lower dependency on external funding.
- **Collaborative development focuses heavily on rules and synergy within the partnership:**
  1) Demand for overseas regulatory consultancy and filing support reaches its highest value across all groups (82.8%), highlighting the complexity of coordinating registration strategies, data package requirements, and communication mechanisms between two parties across different regions under the collaborative development model.
  2) Demand for contract negotiation and legal due diligence (65.5%) and for IP due diligence and patent positioning (55.2%) are significantly higher than in other groups with established expansion strategies. In deeply integrated collaborative development, clearly defining IP ownership, the distribution of rights, and decision-making mechanisms is critical to the success of the cooperation and represents an area with high potential risk.
- **Licensing focuses on value realization:**
  1) Overseas regulatory consultancy and filing support (73.3%) and strategic and transaction advisory (72.2%) form a dual core; the former provides critical regulatory endorsement for product valuation and deal negotiations, while the latter involves identifying the best buyers, designing transaction structures, and maximizing asset value.
  2) Demand for contract negotiation and legal due diligence is quite high (60.0%); licensing agreements are typically complex, involving discussion points such as upfront payments, milestones, sales royalties, and rights ownership, making professional legal support vital.
  3) Demand for overseas resource matching for clinical CROs is also high (46.7%), likely because enterprises need to complete specific clinical research stages—such as proof of concept (POC) validation—to enhance the project's appeal and secure more favorable terms in the transaction.
- **NewCo focuses on architectural setup:**
  1) Overseas regulatory consultancy and filing support, together with strategic and transaction advisory (both at 73.2%) are again tied for the top position; this reflects that establishing a new entity from scratch overseas requires deep support in both commercial architecture (company location, shareholding structure, governance models, etc.) and local regulations (company law, tax law, drug regulation, etc.).
  2) Demand for contract negotiation and legal due diligence is also prominent (63.4%), covering not only agreements with partners but also various legal documents involved in the incorporation process, such as shareholder agreements and articles of association.

These findings suggest that companies should seek and integrate external resources in a targeted manner based on their current stage and established strategy to bridge their own capability gaps. At the same time, this points the way for service providers: offering a one-size-fits-all service is no longer sufficient to meet market demand. Only by providing customized, modular solutions based on an enterprise's specific strategy and pain points can providers secure a place in the industry of assisting Chinese innovative medicines in going global.

Having clarified the urgent need for external support, the survey further explored the capabilities that Chinese pharmaceutical companies believe service providers currently lack. These results not only reflect the actual needs of Chinese firms but also provide clear guidance for service providers to optimize their service models.

Firstly, 69.34% of surveyed enterprises believe that service providers most lack authentic overseas resources and case studies. This indicates that when entering international markets, Chinese developers seek market entry experience proven through practice, mature BD networks, and successful case studies to reduce uncertainty and avoid potential risks. Companies prefer to collaborate with service providers who possess deep overseas networks, practical operational experience, and a wealth of accumulated cases to obtain guidance that is more actionable and offers a higher probability of success.

Secondly, a deep understanding of the pain points faced by Chinese pharmaceutical companies during global expansion represents 53.28%. This reflects that, during the expansion process, Chinese firms face unique and deep-seated challenges in addition to general Internationalization hurdles. If service providers fail to understand these localized challenges, the solutions they offer may remain superficial and fail to address the actual problems their clients encounter.

Thirdly, team configurations with international backgrounds and localized service capabilities were mentioned by 49.64% of respondents, highlighting the demand for professional backgrounds and local service capacity. The ideal service provider should possess a global perspective and international project experience while understanding Chinese market characteristics and corporate culture, thereby effectively bridging the gaps between the Chinese, European, and US markets while providing customized services that meet local needs.

Furthermore, end-to-end, one-stop service capabilities received 35.77% attention, ranking fourth. This indicates that enterprises hope service providers can offer full-chain support—from market research, strategy formulation, and regulatory registration to clinical development and commercial operations—to reduce the complexity and cost of coordinating with multiple providers. One-stop services enhance expansion efficiency through smooth transition of processes and efficient transfer of information.

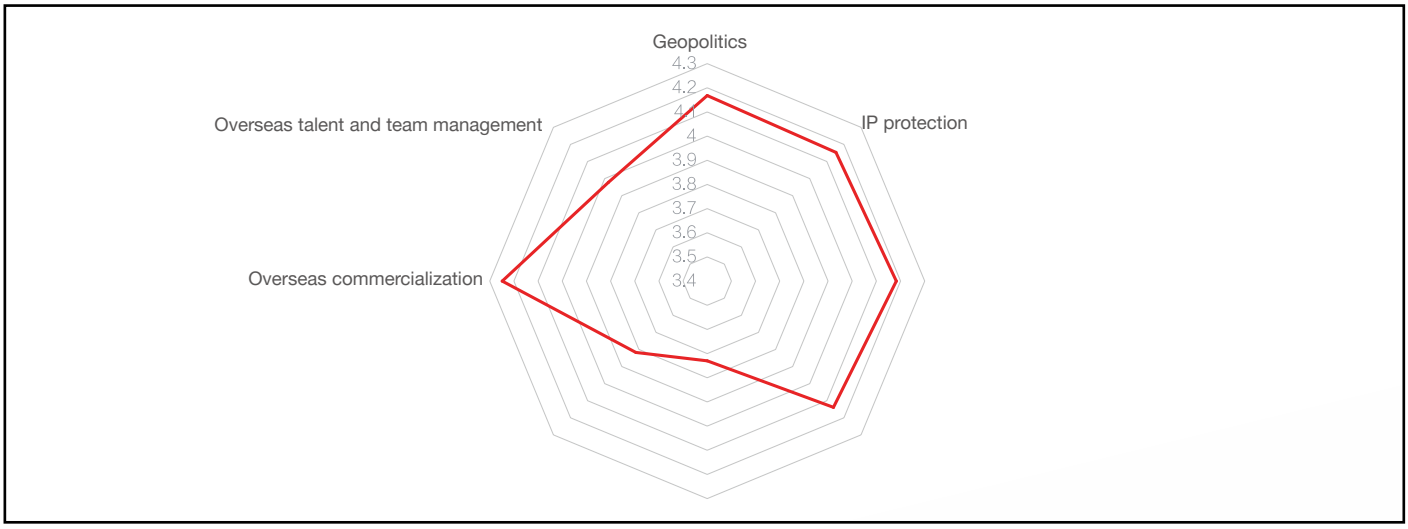
Finally, transparent pricing and success rate disclosures was cited by 30.66% of firms, reflecting the demand for trust and risk management from Chinese pharmaceutical companies. Clear, public fee standards and evidence-based success rate disclosures based on data help enterprises evaluate the value of collaboration more objectively, reduce decision-making risks, and establish a partnership based on mutual trust.

Taken together, these survey results clearly depict the expectations of Chinese pharmaceutical companies for external support during their international expansion. For service providers, there is a need to address these perceived deficiencies to improve service quality and suitability, thereby winning the favor of Chinese pharmaceutical firms.

2.2 Key challenges

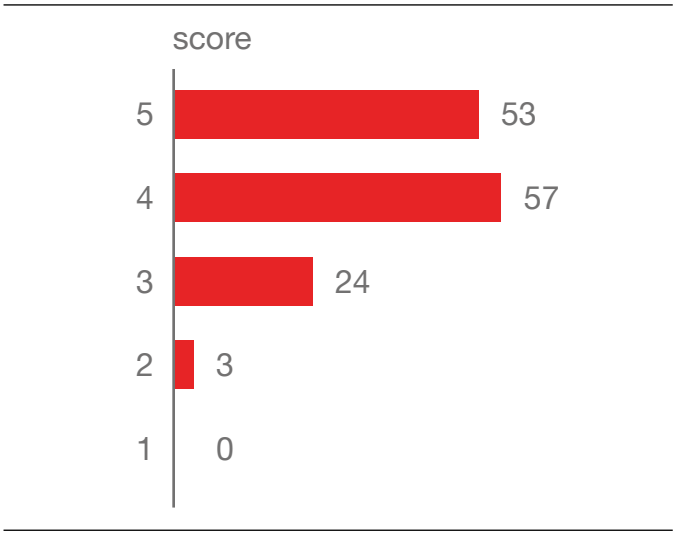
In the pursuit of international markets, Chinese pharmaceutical companies face a series of complex and interconnected challenges. These hurdles are interwoven across political environments, regulatory access, clinical development, commercial operations, and talent organization; any single factor can determine the success or failure of global expansion (Figure 13).

Figure 13. Key challenges for Chinese pharmaceutical companies going abroad, rated by significance



Geopolitics (High importance: 80.3%)

Figure 14. Key challenges: Geopolitics.



Data source: PharmCube survey.

Geopolitics is one of the most prominent challenges for Chinese innovative drug developers during their international expansion. According to the survey results, 80.3% of enterprises rated this factor as high importance, with 38.7% scoring it a 5 and 41.6% scoring it a 4 on a scale of 1 to 5, reflecting deep-seated concerns regarding related risks.

This challenge is primarily manifested in the ongoing deepening of the Sino-US technology rivalry, specifically the legislative progress of the US Biosecure Act (hereinafter referred to as "the Act") and the resulting uncertainty in transaction reviews. In October 2025, the US Senate passed the National Defense Authorization Act (NDAA) for Fiscal Year 2026, which included a revised version of the Act. Although the current version is more moderate than earlier drafts—no longer explicitly naming specific companies and providing clear channels for appeal and mitigation for affected firms—its restrictive scope extends broadly to critical R&D services and equipment, such as CROs and CDMOs. Should a supplier be designated as a "firm of concern", it would directly impede R&D progress. This may force Chinese pharmaceutical companies to re-evaluate and optimize their global manufacturing configurations, supply chain layouts, and data flow arrangements, thereby significantly increasing operating costs and management complexity.

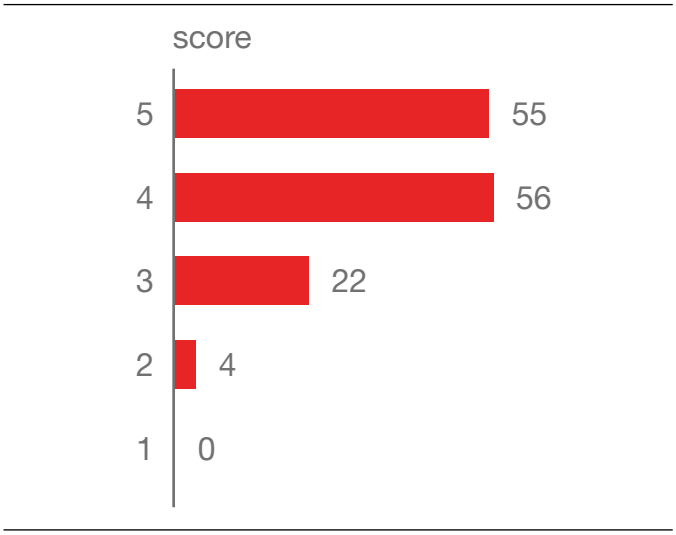
Furthermore, the US Department of Justice issued Executive Order 1411711, which restricts the cross-border transfer of sensitive personal data, indicating that geopolitical pressure is now deeply embedded in the biopharmaceutical industry. The policy not only sets extremely low regulatory thresholds for human omics and bulk health data (such as genomic data involving as few as 100 individuals) but also extends its oversight to key operational links, including clinical trial collaborations and the employment of international talent. Combined with the potential for stricter scrutiny of US pharmaceutical companies acquiring drug rights from China12, mandatory reviews of cross-border licensing transactions by the Committee on Foreign Investment in the US (CFIUS), and the FDA's cautious stance on the applicability of data derived solely from Chinese clinical trials, these policies introduce substantial uncertainty. Ultimately, this may diminish pipeline value and slow the pace of international expansion.

Response strategies for Chinese companies include:

- Proactively building more resilient global cooperation networks to reduce dependence on any single market
- Prioritizing leading service providers with global reputations and proven compliance records, leveraging their internationally recognized compliance systems to endorse pipelines
- Pre-emptively entering emerging markets along China's Belt and Road initiative to diversify target markets and create strategic synergies
- Actively consulting government policy communication platforms to stay informed of regulatory dynamics

Regulatory barriers (High importance: 81.0%)

Figure 15. Key challenges: Regulatory barriers.



Data source: PharmCube survey.

Significant differences in registration and review policies across different countries and regions constitute one of the main challenges faced by Chinese developers going abroad. In the survey, this factor received high priority, with 55 respondents (40.1%) giving it a 5-point rating and 56 (40.9%) giving it 4 points. In total, 81.0% of surveyed enterprises view this as a high-significance challenge, with its score ranking among the highest.

The main difficulties regarding regulatory barriers lie in information asymmetry and high compliance thresholds. There are distinct differences between major regulatory bodies in terms of review pathways, clinical data requirements, acceptance of real-world evidence, and priority review mechanisms. When expanding abroad, Chinese firms often lack timely and accurate interpretations of regulatory dynamics in target markets. This leads to repeated adjustments of clinical development plans, frequent modifications to adaptive designs, and CMC compliance challenges. Ultimately, this results in time delays, wasted resources, and a substantial increase in R&D costs, directly impacting the choice of expansion pathways and overall timelines.

In 2017, China officially joined the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use). To date, domestic regulator the National Medical Products Administration (NMPA) has largely completed the implementation of all 69 ICH guidelines, fully adopting international technical requirements for drug R&D and registration. This marks the alignment of China's technical requirements for drug registration with international standards. However, at the practical regulatory level, mutual recognition still faces immense obstacles. Even in the Hong Kong Special Administrative Region (HKSAR), regulatory mutual recognition or simplified marketing approval for innovative drugs from mainland China has not yet been achieved; innovative drugs approved in the mainland cannot be launched directly in Hong Kong, and barriers in other countries and regions are even more complex.

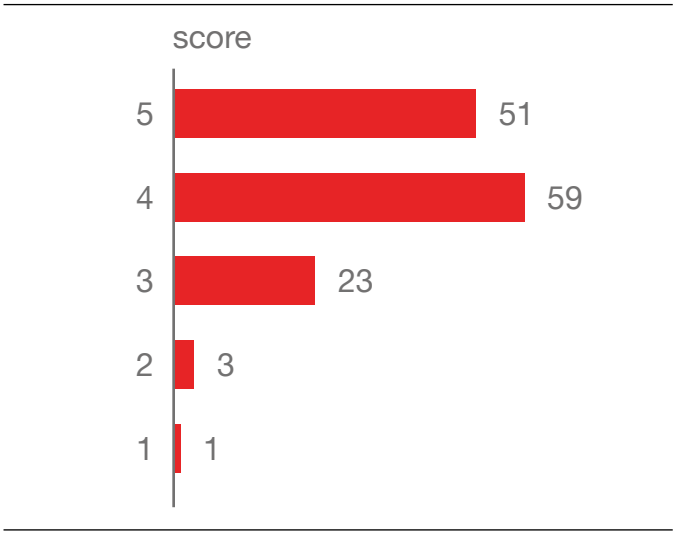
In 2023, China applied to join the Pharmaceutical Inspection Co-operation Scheme (PIC/S). By establishing unified GMP inspection standards, promoting inspector training, and fostering international cooperation, PIC/S members can achieve mutual recognition of drug inspection results. This significantly reduces redundant inspections, lowers compliance costs for companies, and facilitates exports. However, China is not expected to receive approval until 2029 at the earliest. This creates a stark contradiction with the explosive growth of China's innovative drug industry and the urgent need to rapidly develop international markets.

Response strategies for Chinese enterprises include:

- Devising different registration strategies based on pipeline indication characteristics and target market priorities
- Engaging overseas regulatory experts during the early protocol design phase
- Fully utilizing accelerated approval pathways provided by the FDA and EMA
- Partnering with professional service providers to track regulatory policy dynamics and review trends in real time

Overseas clinical trials (High importance: 80.3%)

Figure 16. Key challenges: Overseas clinical trials.



Data source: PharmCube survey.

Executing clinical development in an efficient and compliant manner on a global scale has become a major bottleneck for the international expansion of Chinese innovative drugs. According to the survey results, approximately 80% of enterprises (80.3%, including 37.2% scoring it a 5 and 43.1% scoring it a 4) rated this dimension as high importance (4–5 points).

This challenge is primarily manifested at three levels. Firstly, clinical protocol design must fully accommodate MRCT requirements while considering ethnic differences, variations in indications, and regulatory expectations (such as the FDA's weighting requirements for Asian population data). These factors require Chinese firms to possess a global perspective and forward-looking layout during the early protocol design stage; otherwise, they risk repeated protocol adjustments, extended review cycles, or even being required to conduct supplementary trials.

Secondly, the selection and management of clinical CROs is critical. Chinese pharmaceutical companies need to screen service providers that possess global multi-center operational experience, rigorous compliance capabilities, and controllable costs to ensure that clinical data quality fully complies with ICH-GCP standards. They must also address the coordination difficulties arising from the review processes of ethics committees, timelines, and cultural differences across various countries and regions.

Thirdly, central laboratory management poses a challenge. Overseas international multi-center trials face more complex central laboratory management than domestic ones. To ensure sample integrity, consistency, and compliance, enterprises must: 1. Pay attention to sample transport and enforce strict logistics control; 2. implement unified Standard Operating Procedures (SOPs) for analysis and testing with international regulatory accreditation; and 3. ensure data can pass audits and inspections.

Response strategies for Chinese enterprises include:

- Incorporating an international regulatory perspective from the early stages of clinical development to design a pathway that aligns with the regulatory requirements of major markets, including China, the EU, and the US. Protocol designs can integrate adaptive trial designs and diversified participant recruitment strategies to increase the trial plan's chances of acceptance across different regulatory systems and reduce the risk of major adjustments caused by regional differences later in the process. Employing adaptive designs and inclusive recruitment ensures the protocol simultaneously meets the requirements of multiple regulatory bodies, including the FDA and EMA
- Ensuring that the protocol design focuses not only on scientific rigor and registration value but also on a thorough assessment of feasibility of execution Enterprises should conduct in-depth research into the epidemiology of target diseases, regional competitive landscapes, and participant accessibility, while carefully selecting countries, research centers, and partner institutions. Partners and subject matter experts should be invited to participate in protocol feasibility assessments. It is particularly important to verify that the trial design is consistent with the local Standard of Care (SoC) to avoid situations that are viable in theory but difficult to implement in local clinical practice.

- Establishing a systematic layout for laboratory and supply chain systems as early as possible. Priority should be given to central laboratories and medical imaging service providers with experience in international multi-center projects to ensure validated testing methods and controllable turnaround times. SOPs for sample handling must be unified to ensure consistency during the pre-analysis phase, including collection times, processing limits, cryopreservation conditions, and temperature control requirements. For critical testing methods, methodological validation should be completed early, and backup plans prepared to enhance the stability and risk-resistance of the study. Logistics for investigational medicinal products (IMP) and biological samples should be planned in advance, taking full account of local regulatory, customs clearance, and transport requirements. In practice, this can involve using regional warehousing hubs, fast-track customs clearance partners, standardized labeling, and localized packaging to improve cross-border supply efficiency and mitigate risks. Key compliance documents, such as sample transfer permits and Material Transfer Agreements (MTAs), should also be prepared and secured early.
- Prioritizing strategic partners with end-to-end global service capabilities to minimize management friction caused by fragmented collaboration between multiple service providers. Companies can improve cooperation, execution, and project efficiency by signing framework agreements, setting milestone performance mechanisms, and conducting joint monitoring, thereby creating a stable and controllable global clinical operations system. It is thus advisable to select strategic service providers with end-to-end global capabilities and enhance cooperation through framework agreements, milestone assessments, and joint monitoring.

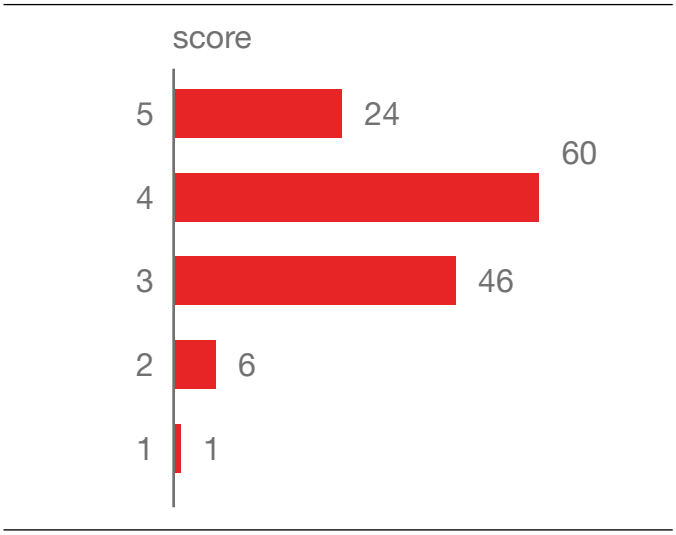
In this process, when advancing clinical research overseas, Chinese pharmaceutical companies often need to leverage partners with global experience, developed professional capabilities, and flexible execution models to better navigate the complex challenges of cross-regional clinical development. Consequently, CROs with a global footprint and integrated service capabilities are increasingly becoming a vital supporting force in the international expansion of innovative drugs.

Using Thermo Fisher's integrated CDMO and CRO services model as an example, the firm has accumulated extensive project experience in the field of global clinical development, with services covering numerous therapeutic areas and multiple stages of drug development, including early-stage research, clinical operations, laboratory testing, and pre- and post-market support. Relying on a vast global network, long-term international project execution experience, and capabilities such as digitalization and patient recruitment tools, service platforms of this kind can, to a certain extent, help enterprises enhance the efficiency, quality, and synergy of international clinical development.

Overall, against a backdrop of continuously rising requirements for global clinical development, partners possessing end-to-end support capabilities and international execution experience are expected to provide more robust support for Chinese innovative pharmaceutical companies going abroad.

Overseas manufacturing (High importance: 61.3%)

Figure 17. Key challenges: Overseas manufacturing.



Data source: PharmCube survey.

Overseas clinical manufacturing (CMO/CDMO) is a challenge for which attention among Chinese innovative pharmaceutical companies is relatively divided, yet its strategic importance remains prominent. According to the survey results, approximately 61.3% of surveyed enterprises rated this dimension as high importance (4–5 points), with 17.5% (24 firms) giving it a 5 and 43.8% (60 firms) giving it a 4.

China has already developed rather complete clinical and commercial manufacturing capabilities. Some leading CDMOs have passed on-site inspections by major regulatory bodies such as the FDA and EMA and possess compliance capabilities that meet international standards. This allows enterprises to effectively reduce initial costs and supply chain complexity by combining overseas filing with domestic manufacturing. Consequently, for many Chinese drug developers with early-stage pipelines or limited resources, the urgency of overseas clinical manufacturing has diminished to some extent.

However, Chinese pharmaceutical firms still face issues such as insufficient localization of production bases, the strict enforcement of international GMP standards, risks in cross-border supply chain transport, and potential pressures from geopolitical or regulatory scrutiny.

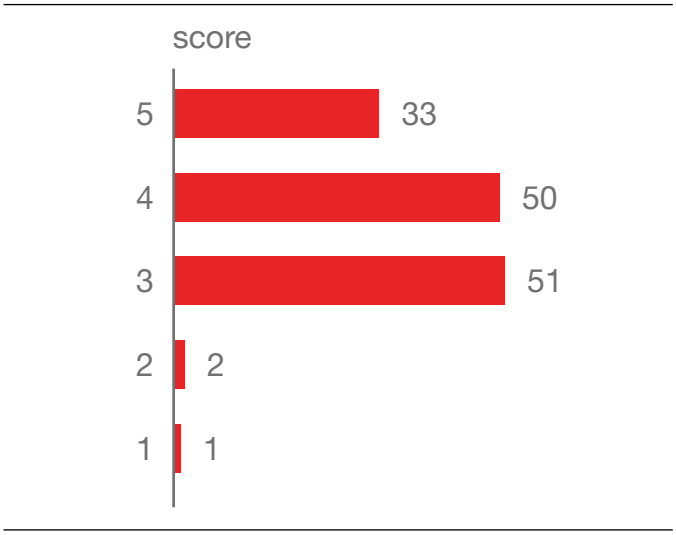
Simultaneously, as some overseas markets tighten their scrutiny of clinical data and manufacturing sources, companies need to plan globalized production strategies in advance to ensure supply chain stability and localized support, thereby avoiding the uncertainty caused relying solely on domestic capacity.

Response strategies for Chinese enterprises include:

- Establishing deep collaborations during the early stages of development with service providers that possess globally diversified manufacturing networks, top-tier compliance records, and powerful technical platforms
- Recognizing that during the overseas clinical manufacturing and subsequent scale-up phases, Chinese firms primarily require platform-based partners with globally diversified production networks, solid compliance records, and the ability to manage transitions across different development stages. Such partners can typically cover process development, clinical sample manufacturing, sterile filling, packaging and logistics for clinical trials, and a degree of regulatory support. Taking service systems like Thermo Fisher Scientific's pharma services model as an example, their value lies not just in production capacity but in helping enterprises improve compliance flexibility and supply stability of overseas clinical manufacturing, thereby reducing execution uncertainties linked to production processes

Overseas supply chain (High importance: 60.6%)

Figure 18. Key challenges: Overseas supply chain.



Data source: PharmCube survey.

The overseas supply chain is a critical risk point that Chinese pharmaceutical companies must continuously manage and optimize during global operations. According to the survey results, 60.6% of respondents (83 firms, with 24.1% scoring it a 5 and 36.5% scoring it a 4) rated this dimension as high importance (4–5 points), reflecting a level of concern similar to that of overseas clinical manufacturing. This indicates that as Chinese pharmaceutical firms expand abroad, their perspective on the supply chain is shifting from the simple supply of materials to compliance and risk assurance.

The main difficulty of this challenge lies in the uncertainty of cross-border procurement for active pharmaceutical ingredients (APIs), intermediates, excipients, and equipment. Furthermore, information asymmetry in service provider selection, discrepancies between CMC quality standards and overseas regulatory requirements, coupled with insufficient supply chain control and information transparency, may further affect the long-term stable supply of critical materials.

Response strategies for Chinese enterprises include:

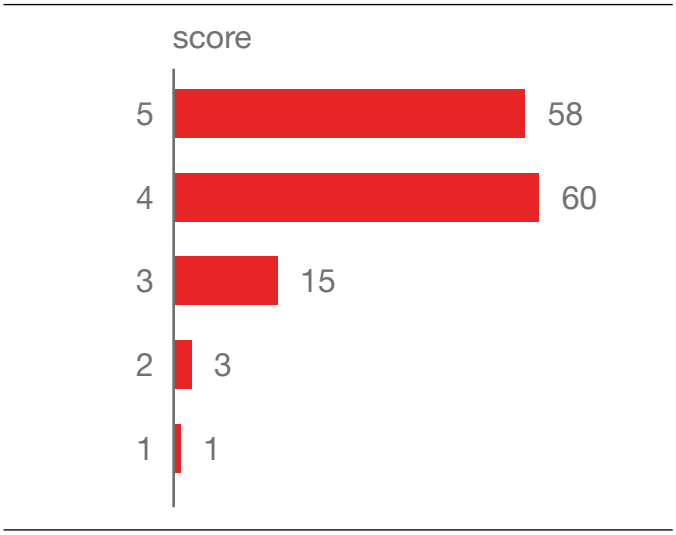
- Building a systematic, risk-oriented supply chain management system through the multi-dimensional screening of compliant service providers
- Strengthening supply chain control and information transparency by developing comprehensive supply chain transparency checklists and risk monitoring systems covering the entire chain
- Establishing dual-sourcing or multi-center production backup mechanisms for critical materials

Faced with a complex overseas supply chain environment, Chinese pharmaceutical companies should prioritize establishing deep strategic partnerships with top-tier service providers that possess global trust and a reputation for compliance, internalizing the service provider's global compliance system as their own competitive advantage.

Relying on a global bioprocessing raw material and equipment platform, Thermo Fisher has built widespread trust within the global biopharmaceutical development and manufacturing ecosystem. Represented by Gibco™ cell culture media, single-use technologies (such as DynaDrive™ and HyPerforma™ single-use bioreactors), chromatography and purification resins, filtration and separation products, and the Applied Biosystems™ SEQ analytical testing portfolio, Thermo Fisher provides quality, compliance, and traceability support from process development to scale-up for various drug modalities—including mAbs, BsAbs, ADCs, mRNA, cell and gene therapies, and vaccines. This helps enterprises establish the data, process, and supply foundations required for global filings earlier, thereby increasing confidence in meeting the requirements of international regulatory bodies such as the FDA and EMA regarding quality systems, document consistency, and manufacturing controllability.

Overseas commercialization (High importance: 86.1%)

Figure 19. Key challenges: Overseas commercialization.



Data source: PharmCube survey.

Overseas commercialization is the decisive last mile in the international expansion of Chinese innovative drug companies; the complexity and significance of this challenge are particularly prominent in this survey. According to the results, a staggering 86.1% of surveyed enterprises (118 firms, with 42.3% scoring it a 5 and 43.8% scoring it a 4) rated this factor as high importance (4–5 points)—a proportion significantly higher than all other dimensions.

Most Chinese pharmaceutical firms lack commercialization infrastructure in mainstream markets such as Europe and the US, including localized sales teams, market access specialist teams, distribution channels, and government affairs capabilities to support medical insurance negotiations and hospital access. Building a mature, compliant, and efficient commercialization team from scratch requires not only massive capital investment but also a lengthy cycle of talent recruitment, cultural integration, and compliance system construction. This is usually unbearable for biotech companies with limited resources and typically only a few projects.

At the operational level, even if a candidate is successfully approved, Chinese firms must navigate overseas medical insurance access and post-access market penetration. The low-price systems formed by China's Social Medical Insurance (SMI) negotiations may be cited by emerging markets as pricing benchmarks, reducing overseas selling prices. Meanwhile, profit margins in European and US markets may be constrained by high promotional costs and competitive landscapes.

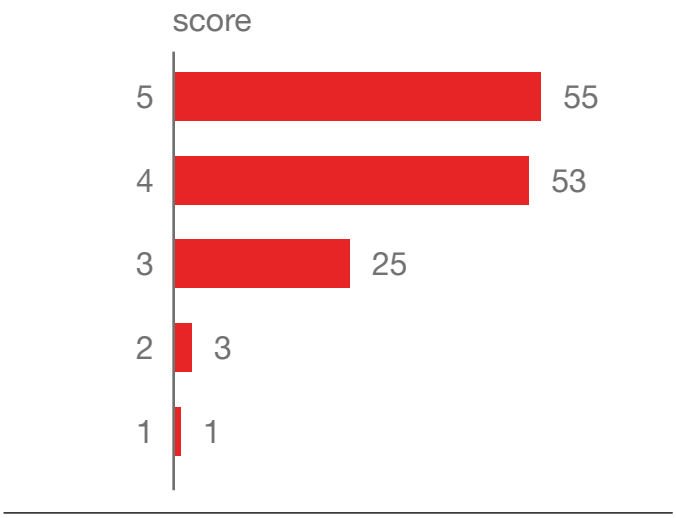
Response strategies for Chinese enterprises include:

- For leading pharmaceutical firms, establishing small but elite in-house Medical Science Liaison (MSL) teams in key European and US markets, while outsourcing distribution and medical insurance negotiations to mature local service providers to reduce initial costs through a hybrid model
- For early-stage or resource-limited biotechs, prioritizing out-licensing or NewCo models to leverage a partner's mature channels for rapid scaling
- Preparing health economics evidence in advance to provide support for medical insurance negotiations and pricing

Around the time of product approval, companies face more than just the completion of registration; they face continuity challenges in the transition to commercial manufacturing, packaging release, and regional market supply assurance. Platform partners like Thermo Fisher are better suited to handle technology transfers, clinical trial supply chain services, commercial manufacturing, and post-launch supply assurance, rather than front-end commercial functions such as market access or sales and promotion. For Chinese drug developers, the key value of this type of collaboration lies in increasing the certainty of delivery as a product moves from the clinic to the market stage.

IP protection (High importance: 78.8%)

Figure 20. Key challenges: IP and Litigation.



Data source: PharmCube survey.

Intellectual property (IP) protection and litigation risk are critical challenges concerning the security of core assets and market access rights during the international expansion of Chinese innovative pharmaceutical companies. According to the survey results, 78.8% of enterprises (with 40.1% scoring it a 5 and 38.7% scoring it a 4) rated this dimension as high importance (4–5 points).

This challenge is primarily manifested in the complexity of overseas patent layouts, the difficulty of Freedom-to-Operate (FTO) analysis, and the high risk of potential infringement litigation. The strength of protection for a Chinese pharmaceutical firm's core compound patents, formulation patents, or process patents in target markets often faces uncertainty; meanwhile, firms must remain vigilant against the possibility of infringement lawsuits initiated by originator companies or competitors.

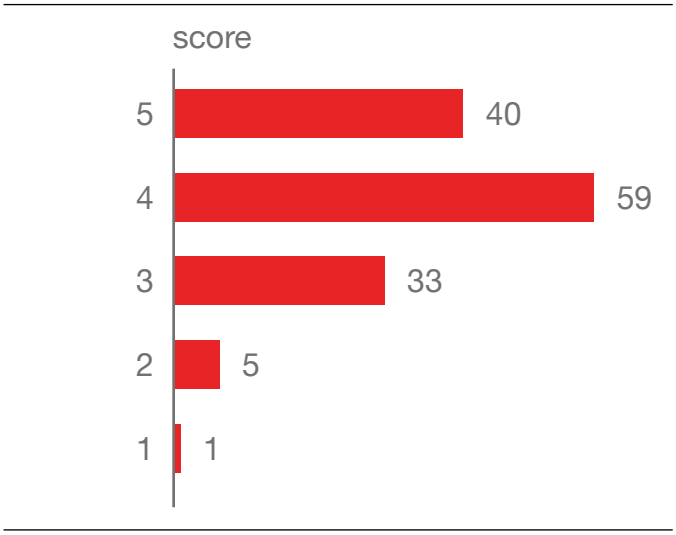
Particularly in the US market, the Paragraph IV patent challenge system allows generic applicants to file declarations of patent invalidity or non-infringement before a new drug is launched, thereby triggering litigation. Such lawsuits often last for several years, with legal fees for a single party easily reaching millions or even tens of millions of USD, while outcomes remain uncertain. For Chinese companies with relatively limited capital and legal resources, once involved, they may find their commercialization process severely hampered by protracted litigation periods and enormous expenses—regardless of the final verdict—potentially impacting the overall operations of the company.

Response strategies for Chinese enterprises include:

- Establishing a robust IP management system, conducting comprehensive FTO analysis and global patent layouts at the compound discovery stage, and building multi-level, three-dimensional patent families around core molecules
- Developing long-term partnerships with internationally renowned law firms to formulate litigation contingency plans and risk mechanisms

Overseas talent and team building (High importance: 72.3%)

Figure 21. Key challenges: Overseas talent and teams.



Data source: PharmCube survey.

Overseas talent and team building is a highly regarded aspect of internal organizational capacity building during international expansion. According to the survey results, approximately 72.3% of respondents (99 firms, with 29.2% scoring it a 5 and 43.1% scoring it a 4) rated this dimension as high importance (4–5 points).

This challenge is primarily manifested at two levels. Firstly, at the domestic headquarters level, there is a lack of versatile, high-end talent possessing both a global perspective and professional depth. The international expansion of innovative drugs requires more than just specialists in a single field; it demands versatile leaders who possess expertise in international clinical development, registration and filing within complex overseas regulatory environments, and commercial access in mature markets, while maintaining a profound understanding of the Chinese firm's strategy.

Secondly, the recruitment, incentive structures, management costs, and cultural integration of local overseas teams pose significant difficulties. The cost of recruiting for high-end positions—such as overseas medical directors, regulatory affairs specialists, and heads of commercialization—is exorbitant, while retention rates remain low. Friction may also arise between Chinese headquarters and overseas teams due to differences in communication styles, decision-making mechanisms, work pace, and general understanding. This can easily lead to deviations in the execution of headquarters' directives abroad, or a failure to effectively communicate local insights from overseas teams back to decision-makers at headquarters, resulting in team inefficiency.

Response strategies for Chinese enterprises include:

- Clearly defining core competency models for key positions at each stage based on target markets, pipeline stages, and expansion models
- Synchronizing the planning of talent strategies by Prioritizing the allocation of registration and clinical coordination talent during the initial expansion phase, and gradually building scaled local commercialization and medical affairs teams upon entering the commercial stage
- Increasing the retention rate of high-end talent through equity incentives and career path planning, and establishing cross-border collaborative workflows

The international expansion of Chinese innovative drugs faces challenges ranging from macro-geopolitics to micro-operational management. These challenges are interrelated and progressive; a deficiency in any single factor could amplify the overall risk.

However, challenges also contain opportunities. By building stable global cooperation networks, differentiated regulatory response strategies, deep synergies with strategic service providers, and diversified business models, Chinese pharmaceutical companies are expected to gradually resolve these challenges. This will allow them to upgrade from simply going global to walking steadily toward long-term goals. In the future, the international expansion of Chinese innovative drugs will no longer be a simple export of products, but a deep integration of Chinese innovation with the global pharmaceutical ecosystem.

Quotes of experienced buyer

The true test for the international expansion of Chinese innovative drugs is not whether they can enter the global market, but whether they can become a trusted and respected member of the global pharmaceutical innovation ecosystem.

To build global trust, Chinese innovation needs:

- Flagship products: Successful cases of global commercialization are the most persuasive evidence
- Rigorous quality systems: Letting quality speak for itself is the most fundamental source of trust
- Long-term partnerships: Moving beyond short-term cooperation toward deep strategic synergy with global industry leaders
- Sustained contributions to innovation: Achieving continuous innovation akin to a century-old institution, rather than a one-off success

This is a long-term race that tests endurance, systems, and culture. I believe that if we can achieve these goals, looking back in five or ten years, this will be one of the proudest chapters in the journey of China's innovation industry.

— Head of the China innovation center at an MNC

05

Building global trust to realize the global value of Chinese innovative assets

In 2026, China's biopharmaceutical sector was formally established as a national emerging pillar industry. This marks a new starting point, marking the sector's transition from scale-driven growth to a quality-driven phase. Under the domestic structural contradiction between intense competition and weak payment systems, going abroad is an inevitable choice to reshape innovation value, obtain diversified funding, and achieve sustainable R&D. China has demonstrated global leadership in cutting-edge technologies such as ADCs and bispecific/multi-specific antibodies, laying a solid foundation for Chinese enterprises to seek a new standing within the global industrial chain.

In the current international geopolitical and regulatory environment, certainty has become the scarcest attribute in cross-border transactions. International expansion will be centered on winning through certainty:

1. Clinical certainty: Scientific product advantage is the cornerstone. Only assets rooted in unmet global clinical needs that possess first-in-class potential or clinical differentiation can gain approval from overseas regulatory bodies and recognition from demand-side partners.
2. Compliance certainty: Robust clinical data and a manufacturing and supply system that complies with international cGMP standards are key to going abroad. Multi-regional clinical trials (MRCTs) should serve as the default pathway for global development to ensure that data remains flawless under global regulatory scrutiny.
3. Delivery certainty: By integrating with CROs and CDMOs that possess proven global compliance records, enterprises can gradually refine their own compliance systems and leverage them against competitors.

The coexistence of multiple expansion models will persist, with demand in emerging markets set to increase gradually. Expansion pathways are the result of balancing resources against risk tolerance, are expected to diverge into two main directions:

a) Scientific expansion of standardized products: Delivering Chinese assets with high levels of standardization and high-quality clinical data to the global market to realize the value of scientific product advantages.

b) Systemic expansion of full-chain capabilities: Independently building or integrating global resources to export complete R&D, registration, manufacturing, and commercialization capabilities, thereby realizing value in both mainstream Western markets and emerging markets.

Future victors will be those companies capable of transcending geopolitical games. By establishing partnerships with world-class CROs and CDMOs, they will transform Chinese innovation into certainty recognized by global regulators. At that stage, the global division of labor in innovative drug development will reach a new equilibrium. China will become the main hub for global early-stage drug discovery and rapid Proof of concept (POC). Rooted in global innovation needs, China's high-quality, high-efficiency innovative activities will be integrated into the global innovation ecosystem, accelerating the benefits of Chinese innovation for patients worldwide and maximizing its own value within the industrial chain.

From lab to patient, Thermo Fisher empowers China's pharmaceutical innovation across the full value chain

Trusted products and services

Equipment, reagents, and consumables along life cycle

patheon™ ppd

360° CDMO and CRO solutions

Life Science tools enabling cutting edge research

Global standard for bioproduction

Choice of global pharma

Partner for all top 50 MNCs

50+

Partner for all Top 50 MNCs

2700+

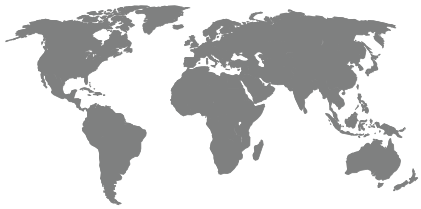
Biotech companies in past 5 years

In-depth understanding of buyers' needs

Rich experience of global practices

Global footprint to support

150+ operation sites globally



Global CRO & CDMO network

Global standard & regulations (FDA, GxP)

Providing end-to-end support across the value chain, from drug discovery to commercialization

Research & discovery

Process dev. & optimization

Pre-clinical phase

Clinical phases I-III

Commercialization & production

Supporting you with innovative technologies to enable cutting-edge therapeutic research

Drug Discovery

Mass Spectrometry and Affinity based proteomics solution

Invitrogen™ Bigfoot™ Cell Sorter

Thermo Scientific™ Orbitrap™ Astral™ Zoom MS

Olink

High throughput proteomics assay

Visualization based structural biology solution

Thermo Scientific™ Arctis™ Cryo-Plasma FIB

Thermo Scientific™ Krios™ 5 Cryo-TEM

Translational Science

Multi-disciplinary approach that bridges basic research and clinical applications

Thermo Scientific™ Glacios™ 2 Cryo-TEM

Invitrogen™ Attune™ Xenith™ Flow Cytometer

Thermo Scientific™ KingFisher™ APEX Sample Purification System

Thermo Scientific™ Orbitrap™ Excedion™ Pro MS

Gibco™ Cell Therapy System media and reagents

Invitrogen™ Gene synthesis & cloning kit

Companion Diagnostics

Unparalleled experience & track record as the globally distributed NGS CDx

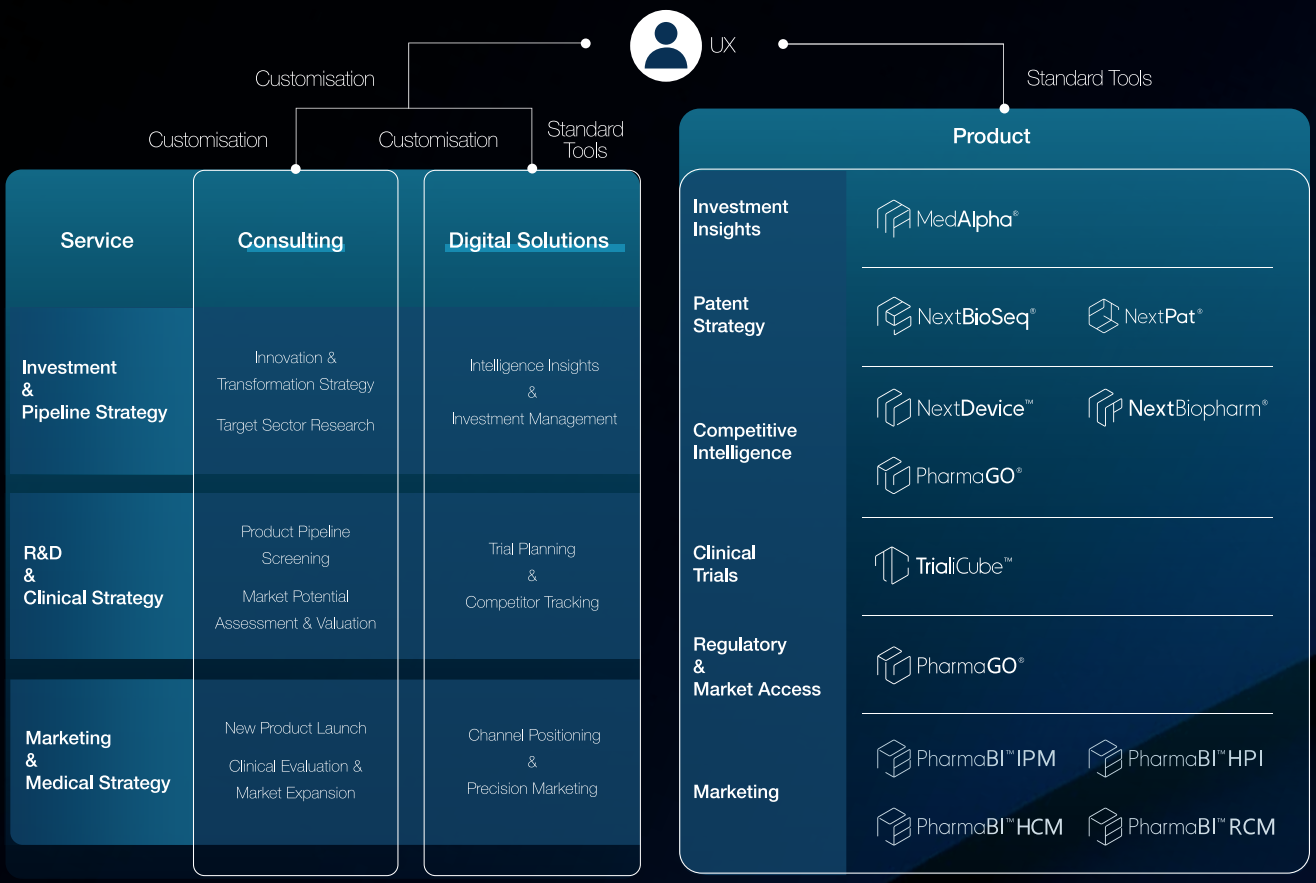
Ion Torrent™ Genexus™—Fully Automated NGS

2 Touch Points (10 min)
Automated, 1-day Results

Stellar™MS

PHARMCUBE

Data Intelligence & Consulting



Value

PharmCube Data Middleware Platform | Achieving Cross-database Insights

Core Base	Drug Big Data	Data Scientist + AI	Pharmaceutical Industry Experts

A RELIABLE DATA PARTNER FOR PHARMACEUTICAL INNOVATION AND INVESTMENT

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