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China's Innovative Drug Industry: Navigating Growth, Policy, and Globalization

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Part I: Executive Summary

China's innovative drug industry is at a critical juncture, its trajectory shaped by a powerful duality of forces: on one hand, the state's unwavering determination to foster innovation, and on the other, immense pressure to control costs and reshape the market. This "policy squeeze" has catalyzed an unprecedented surge in R&D output and fueled corporate ambitions for globalization. However, it has also intensified the crisis of R&D homogenization ("involution") and compelled the industry to pivot towards licensing-out as a primary strategy for value realization.

This report delves into the core drivers and challenges shaping the future of China's innovative drug sector. Key trends include:

1. **A Maturing Policy Framework:** Since 2015, China has established a full-chain policy support system covering R&D, review, payment, and clinical application. This system, however, exhibits a distinct duality. Reforms in drug review and approval (CDE reform) and alignment with international standards (accession to ICH) have

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significantly accelerated the market entry of new drugs. Concurrently, mechanisms such as the National Reimbursement Drug List (NRDL) negotiations and Volume-Based Procurement (VBP) have exerted formidable downward pressure on drug prices through the logic of "trading price for volume" and "emptying the cage for new birds."

2. **The Prominent "Innovation Paradox":** Spurred by policy incentives, the number of innovative drug pipelines in China has surged to the top of the global ranks. Yet, this explosive quantitative growth is accompanied by severe homogenization. R&D resources are excessively concentrated on a few validated "hot" targets like PD-1, HER2, and BCMA, leading to fierce "involutionary" competition that compresses the market value and return on investment for true First-in-Class (FIC) innovations.
3. **Strategic Shift Amidst a "Capital Winter":** Following a peak in 2021, investment and financing activities in the biopharmaceutical sector have cooled sharply, entering a "capital winter." Difficulties in primary market financing and tightening IPO channels have forced many biotech companies to seek non-dilutive funding. This has directly led to a boom in license-out deals, with upfront payments now surpassing concurrent primary market financing, making it a crucial avenue for validating innovation and securing cash flow.
4. **Gradual Perfection of the IP System:** China has established a drug patent linkage system and a Patent Term Extension (PTE) system in line with international standards, providing a legal cornerstone for innovation. However, compared to mature markets like the US, Europe, and Japan, China's PTE system remains somewhat limited in scope and compensation, reflecting a cautious policy balance between encouraging innovation and promoting competition from generic drugs.

Looking ahead to 2025-2030, the core proposition for China's innovative drug industry will be how to escape the "innovation paradox" and transition from quantitative leadership to qualitative excellence within the "policy squeeze" environment. Future success will depend on the industry's ability to effectively address homogenization,

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strike a balance between capital efficiency and globalization strategy, and ultimately transform from an efficient global R&D engine into a global biopharmaceutical powerhouse with genuine source innovation capabilities.

Part II: The Evolving Policy Superstructure: A Duet of Incentive and Restraint

The most fundamental driver behind the rise and evolution of China's innovative drug industry is its top-down policy architecture. Since 2015, a series of profound reforms has reshaped the entire ecosystem, creating a complex system that integrates incentives and constraints, support and screening. Understanding this policy duality is key to grasping the industry's future direction.

2.1 The "Full-Chain" Support System: An Ambitious Blueprint for an Innovation Ecosystem

In recent years, the Chinese government has clearly expressed its determination to elevate the biopharmaceutical industry to a strategic national priority. Through a series of coherent policy documents, it has constructed a support network designed to cover the entire lifecycle of an innovative drug, from the laboratory to the bedside.

- **Foundational Policy Framework:** The starting point of this reform wave can be traced to the State Council's 2015 "Opinions on Reforming the Drug and Medical Device Review and Approval System," which aimed to resolve the backlog of drug registration applications and encourage innovation [1]. Subsequent key initiatives included: China's official accession to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) in 2017, marking the comprehensive alignment of China's drug regulatory system with international standards and paving the way for domestic innovative drugs to go global [2]; the formal establishment of the National Healthcare Security Administration (NHSA) in 2018, which unified healthcare insurance management

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functions and laid the organizational groundwork for subsequent payment system reforms [2]; and the implementation of the newly revised "Measures for the Administration of Drug Registration" in 2020, which systematically established four expedited registration pathways—priority review, breakthrough therapy, conditional approval, and special approval—significantly improving the review efficiency for innovative drugs [2].

- **Recent Policy Reinforcement and Continuation:** In the new phase of development, policy support has only intensified. In 2023, the State Council's executive meeting approved the "Action Plan for High-Quality Development of the Pharmaceutical Industry (2023-2025)," which explicitly proposed providing full-chain support to address the "high difficulty, long cycle, and high investment" characteristics of pharmaceutical R&D [2]. In 2024, the Government Work Report for the first time listed "innovative drugs" as a new strategic industry to be actively cultivated [3]. In the same year, another State Council executive meeting approved a policy document on "Supporting the High-Quality Development and High-Level Application of Innovative Drugs Across the Entire Chain," further emphasizing the coordinated use of multiple policy tools, including health insurance payments, price management, and commercial insurance, to support the development of innovative drugs [2, 4].
- **Tangible Results of Reform—Accelerated Review and Launch:** The impact of these policies is most directly reflected in the drug review and approval data. The review efficiency of the Center for Drug Evaluation (CDE) under the National Medical Products Administration (NMPA) has improved significantly, and the backlog issue has been fundamentally resolved [1, 5]. The review period for New Drug Applications (NDAs) has stabilized at approximately 500 days [6]. Encouraged by this, R&D enthusiasm among enterprises has soared. The number of Investigational New Drug (IND) applications for Class 1 new drugs has climbed annually, with the CDE accepting 1,241 Class 1 new drug INDs in 2023, a year-on-year increase of 31.7%, setting a historical record [6, 7]. This series of data

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eloquently proves that an efficient and predictable regulatory environment has taken shape, providing a solid foundation for the vigorous development of innovative activities.

2.2 The "Price-for-Volume" Trade-off: Navigating Reimbursement Access and Volume-Based Procurement

While unleashing innovation, the other hand of policy—payment reform led by the NHSA—has exerted unprecedented pressure on drug prices. The National Reimbursement Drug List (NRDL) negotiations and Volume-Based Procurement (VBP) together form a sophisticated system for market access and price formation, profoundly altering the commercial logic of innovative drugs.

- **The "Reimbursement Cliff"—National Reimbursement Drug List (NRDL) Negotiations:**
    - **Core Mechanism:** The core logic of NRDL negotiations is "trading price for volume" [8]. For innovative drugs with exclusive patents and high clinical value but prohibitive prices, the NHSA organizes centralized negotiations annually. If a pharmaceutical company wants its product included in the national reimbursement scope to gain vast market access, it must accept a significant price cut.
    - **Data and Impact:** Since its establishment in 2018, the NHSA has conducted six rounds of negotiations. The average price reduction for successfully negotiated drugs has consistently been around 60% [9, 10, 11]. For instance, in the 2023 negotiations, 121 drugs were successful, with an average price drop of 61.7% [9]. This model creates a "reimbursement cliff"—the profit margin of an innovative drug is substantially compressed shortly after launch, much earlier than the traditional "patent cliff" caused by patent expiry. This has dramatically changed companies' expectations of a product's lifecycle value [8].
    - **Opportunity and Speed:** Yet, opportunity lies within the pressure. The regular,

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annual nature of NRDL negotiations has drastically shortened the time from approval to reimbursement for innovative drugs. This cycle has shrunk from an average of about 5 years in the past to just over 1 year, with over 80% of innovative drugs entering the NRDL within 2 years of launch [12]. In 2023, 57 products even achieved "approval and inclusion in the same year" [12]. This rapid volume ramp-up effect can lead to a surge in sales in the short term, partially compensating for the loss from price reductions and driving a rapid upgrade in clinical medication structure [10, 12].

- **The "Patent Cliff" and "Emptying the Cage for New Birds"—Volume-Based Procurement (VBP):**
  - **Core Mechanism:** VBP, or "ji-cai," primarily targets generic drugs that have passed the quality and therapeutic equivalence evaluation, as well as some off-patent originator drugs. The model is "linking volume to price," where the state or regional alliances commit to purchasing 50%-80% of the agreed procurement volume of the winning products in exchange for the lowest bids from companies [13, 14].
  - **Direct and Indirect Impact:** The direct consequence of VBP is the extreme compression of profit margins for generics and off-patent originator drugs, with average price reductions often exceeding 50%, and some products even dropping by over 90%. This has truly created a "patent cliff" in the Chinese market [8, 15]. Its more profound indirect impact is the "emptying the cage for new birds" effect. The healthcare insurance funds saved by drastically reducing spending on generics through VBP (e.g., the first four rounds of national VBP saved up to 53.9 billion RMB annually) have freed up precious budget space for paying for high-value innovative drugs included in the NRDL [2, 8, 16, 17, 18].
  - **Strategic Driver:** This combination of mechanisms has fundamentally subverted the traditional profit models of pharmaceutical companies. The era of

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relying on "evergreen" products (i.e., maintaining high prices after patent expiry) is gone. A company's survival and growth now almost entirely depend on its ability to continuously develop innovative drugs with high clinical value that can enter the NRDL during their patent protection period, thereby realizing their value before the VBP "guillotine" falls. This makes innovation a necessity for survival, not an optional extra [14, 15, 19].

This complex policy system is not a simple superposition of policies but a meticulously designed "policy squeeze." Policies like accelerated reviews and higher standards constitute the "offensive" force driving R&D, while NRDL negotiations and VBP form the "defensive" and "screening" forces reshaping the market and controlling costs. The two are interconnected and mutually causal. Funds saved from VBP make it possible to pay for innovative drugs, whose value, in turn, must be confirmed through the rigorous evaluation and price negotiations of the NRDL. This dual pressure has created a highly dynamic, competitive, and uncertain market environment, forcing all participants into a race for innovation and market access at maximum speed and efficiency. In this context, the definition of commercial success has been reshaped: it is no longer about maintaining high prices, but about achieving the broadest market coverage at a reasonable price as quickly as possible. This requires companies to possess a new set of capabilities, including superior clinical development, a deep understanding of health economics, effective government affairs communication, and a flexible market access strategy.

Part III: Market and R&D Dynamics: A Picture of Explosive Growth and Intensifying Homogenization

Driven by this dual policy engine, China's innovative drug market has shown robust growth, and the scale of its R&D pipeline has rapidly expanded. However, beneath this prosperous landscape, the shadow of R&D homogenization ("involution") looms large, posing a core challenge to the industry's sustainable development.

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3.1 Market Trajectory and Therapeutic Area Focus

China has firmly established itself as the world's second-largest pharmaceutical market, and its internal structure is undergoing a profound transformation, with innovative drugs becoming the undisputed core growth engine.

- **Market Size and Growth Drivers:** According to IQVIA forecasts, China's pharmaceutical market is expected to grow from $163 billion in 2023 to $197 billion in 2028 [20]. Behind the steady growth of the overall market is the explosive expansion of the innovative drug segment. In key therapeutic areas like oncology and immunology, sales of innovative drugs soared from 18.1 billion RMB in 2019 to 60.7 billion RMB in 2023, with a compound annual growth rate (CAGR) of 35.3% [17]. Correspondingly, the sales share of innovative drugs in China's core hospital market has risen from 21% in 2015 to 29% in 2024 [4].
- **Growth Divergence between Biologics and Chemical Drugs:** The growth momentum of biologics far surpasses that of traditional chemical drugs, consistent with global trends. In the hospital terminal market, biologics have maintained a CAGR of 12.1% in recent years. In the retail terminal, their growth is even more rapid, with a 28.0% increase in 2023, while chemical drugs grew by only 3.1% in the same period [2]. This reflects an accelerating shift of capital and R&D resources towards the biotechnology sector, which has higher technical barriers and greater innovation potential.
- **Concentration and Expansion in Therapeutic Areas:** Anti-tumor drugs and immunomodulators are currently the largest and fastest-growing therapeutic areas. Their combined market share increased from 13.6% in 2020 to 18.2% in 2024 [2], and they account for 64.4% of total innovative drug sales [7]. This high concentration reflects global R&D hotspots and China's huge unmet clinical needs. Although competition in oncology is fierce, companies have begun to consciously diversify their portfolios, investing more resources in areas such as autoimmune diseases, metabolic diseases (e.g., diabetes), and neurological disorders [21, 22].

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Ophthalmology, in particular, has seen a surge in R&D interest, with its IND application volume showing a five-year CAGR of 31.7% [7].

- **The Rising Strategic Value of the Retail Channel:** The retail pharmacy channel is becoming a crucial outlet for innovative drugs. In 2024, sales in China's physical retail drug market reached 452.7 billion RMB, a growth rate of 5.9%, higher than the 3.3% growth in the core hospital market [23]. This is partly due to the "dual-channel" policy, which allows patients to purchase NRDL-listed drugs at designated DTP (Direct-to-Patient) pharmacies and receive the same reimbursement as in hospitals [23]. Furthermore, due to hospital assessment pressures like the drug-to-revenue ratio, some high-value innovative drugs face difficulties in hospital access, making DTP pharmacies with professional pharmaceutical services and cold-chain capabilities a key out-of-hospital sales channel. Especially in oncology, sales growth in the retail sector far outpaces that in the hospital channel [23]. This indicates that for pharmaceutical companies, the retail channel has evolved from a supplementary channel to a strategic one, parallel to the hospital channel, providing significant market space for self-pay drugs and innovative drugs not yet admitted to hospitals, which are less affected by VBP [23].

Below is an overview of China's pharmaceutical market, clearly showing the scale and growth dynamics of each segment.

Table 1: Overview of China's Pharmaceutical Market (2023-2024)

Metric	Data	Source
Overall Market Size (2024)	1,349.5 billion RMB	[23]
Overall Market Growth (YoY)	4.2%	[23]
Core Hospital Market Size (2024)	896.8 billion RMB	[23]
Core Hospital Market Growth (YoY)	3.3%	[23]
Physical Retail Market Size (2024)	452.7 billion RMB	[23]

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Physical Retail Market Growth (YoY)	5.9%	[23]
Biologics CAGR (Hospital Terminal)	12.1%	[2]
Biologics Sales Growth (2023 Retail)	28.0%	[2]
Chemical Drug Sales Growth (2023 Retail)	3.1%	[2]
Anti-tumor/Immunomodulator Market Share (2024)	18.2%	[2]

3.2 The R&D Pipeline: From Follower to Global Competitor

Driven by market demand and policy incentives, China's innovative drug R&D capabilities have achieved leapfrog development, with pipeline scale and technological complexity reaching globally competitive levels.

- **Global Leadership in Pipeline Scale:** China has become the world's second-largest source of new drug R&D, with a pipeline second only to the United States [24]. By the end of 2024, the cumulative number of active innovative drug pipelines led by Chinese companies reached 3,575, even surpassing the US in sheer numbers [4]. In the global Top 25 ranking of pharmaceutical R&D pipelines, four Chinese companies have made the list: Hengrui Medicine, Sino Biopharmaceutical, Fosun Pharma, and CSPC Pharmaceutical Group [24].
- **Leading Companies Spearheading Innovation:** A group of domestic leaders and emerging biotech companies forms the core of China's innovation engine. Hengrui Medicine, a traditional "innovation leader," boasts one of the largest domestic R&D pipelines (over 280 projects) with a deep focus on oncology and metabolic diseases [21, 24, 25]. BeiGene is known for its high-intensity R&D investment, with R&D expenses reaching 9.538 billion RMB in 2021 alone [26]. In addition, companies like Sino Biopharmaceutical, Fosun Pharma, Innovent Biologics, and Junshi Biosciences hold significant positions in the domestic innovation landscape with their rich pipelines [25, 27].
- **Technological Capabilities Advancing Up the Value Chain:** China's R&D strategy is undergoing a profound transformation from "me-too" innovation to "fast-

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follow" and "me-better," and is progressively moving towards higher-value "Best-in-Class" (BIC) and "First-in-Class" (FIC) innovations [4, 28]. Chinese companies have demonstrated a remarkable ability to learn and catch up in the application of new technology platforms. Currently, cell therapies (28%) and small molecule drugs (19%) are the most numerous in the R&D pipeline, while projects in cutting-edge fields like Antibody-Drug Conjugates (ADCs), bispecific/multispecific antibodies, and gene therapies are also rapidly increasing, showing that Chinese R&D is fully embracing the latest global technological waves [4, 6, 7].

3.3 The Innovation Paradox: The Challenge of "Involution"

Despite significant progress in R&D pipeline scale and technological level, China's innovative drug sector faces a stark "innovation paradox": the unprecedented R&D activity is accompanied by increasingly severe homogenization, or "involution."

- **Definition and Manifestation of "Involution":** "Involution" describes a state of high-level repetitive input where participants compete fiercely in a few limited directions, leading to diminishing marginal returns and harming overall innovation efficiency. In China's innovative drug sector, this manifests as a large number of companies flocking to a handful of market-validated "hot" targets.
- **Empirical Data on Homogenization:**
    - **PD-1/PD-L1 Inhibitors:** This is the most classic case of "involution," with over 10 similar products approved in China and dozens of projects in late-stage clinical trials, leading to extremely fierce competition in indications and pricing [7].
    - **ADC Field:** For HER2-targeting ADC drugs, Chinese companies have 24 projects under development, accounting for 80% of the global ADC pipeline for this target [4].
    - **Cell Therapy Field:** For BCMA-targeting CAR-T therapies, China has 74

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ongoing projects, making up 71% of the global total. For CD19-targeting CAR-T therapies, China has a staggering 149 projects, representing 61% of the global pipeline [4].

Table 2: R&D Homogenization on Key Targets

Target/Technology Platform	No. of Projects by Chinese Cos.	China's Share of Global Pipeline (%)	Example Players	Source
HER2-ADC	24	80%	Hengrui, Bio-Thera, Kelun-Biotech	[4]
BCMA CAR-T	74	71%	Legend Biotech, CARsgen, IASO Bio	[4]
CD19 CAR-T	149	61%	Fosun Kite, JW Therapeutics, Gracell	[4]
PD-1/PD-L1 mAb	30+	59%	Hengrui, BeiGene, Innovent, Junshi	[4]

- **Negative Consequences of "Involution":**

1. **Squeeze on Clinical Resources:** Numerous homogeneous projects compete for limited clinical trial centers and patient resources, driving up R&D costs and potentially compromising trial quality [4].
2. **Shrinking Value Expectation:** Fierce competition drastically shortens the "first-mover advantage" window for FIC drugs. Data shows that in 2024, the market exclusivity period for an FIC innovative drug in China after launch has shrunk to just 12.2 months. Latecomers can quickly enter the market with similar products at lower prices, severely eroding the innovator's return on investment [4].
3. **Mismatch of Capital and Talent:** Guided by both capital and policy, resources are overly concentrated on "fast-follow" projects with high certainty and lower risk. In contrast, investment in true source innovation (0-to-1 breakthroughs), which requires long-term commitment and high risk, is insufficient. In the long

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run, this could solidify China's role as a "follower" in the global innovation chain [29, 30, 31].

The formation of this "innovation paradox" is rooted in the combination of policy pressure and the profit-seeking nature of capital. On one hand, the pressure from healthcare cost control and VBP forces companies to rapidly launch new products to survive. On the other hand, the capital markets in recent years have favored projects with validated targets and relatively higher success rates. These two forces have pushed companies onto the track of "involution." This is not simply redundant construction but a growing pain that China's innovative drug industry must endure as it moves from adolescence to maturity. It reflects the entire ecosystem's difficult exploration in balancing speed with quality, and imitation with originality. How to guide resources from the "red ocean" of low-level repetition to the "blue ocean" of true differentiation will be key to the future success of China's innovative drug industry.

Part IV: The Global Arena: Capital Flows and International Ambitions

Against the backdrop of intensifying domestic competition and sustained policy pressure, going global has become an inevitable choice for Chinese innovative drug companies. However, this path overseas is not a smooth one; it is closely tied to the pulse of global capital markets and presents diversified yet challenging strategic pathways.

4.1 Navigating the "Capital Winter"

Since global biopharmaceutical investment and financing peaked in 2021, the entire sector has rapidly entered a downward cycle, the so-called "capital winter." This trend has had a profound impact on Chinese innovative drug companies, which are highly dependent on financing.

- **A Sharp Cool-down in the Financing Market:** Data shows that since 2021, both

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the total financing amount and the number of deals in China's biopharmaceutical sector have plummeted, hitting a new low in 2024 [2, 32]. The number of financing events in the primary market has reverted to pre-pandemic levels of 2019, but the financing amounts are even lower [32]. At the same time, the channel for public listings has also narrowed significantly. Whether on the Hong Kong Stock Exchange under Chapter 18A or on the STAR Market of the A-share market, the review standards for pre-revenue biotech companies have become increasingly stringent, leading to a sharp decline in the number of IPOs and the amount of capital raised [32, 33].

Table 3: Financing Trends in China's Biopharmaceutical Sector (2021-2024)

Year	Total Financing ($B)	No. of Deals	Avg. Deal Size ($M)	No. of IPOs (HKEX 18A + STAR)	Source
2021	N/A (Peak)	805	N/A	N/A	[2]
2022	61.59	N/A	16	N/A	[33]
2023	N/A	N/A	N/A	N/A	[32]
2024 (Jan-Oct)	42.06	229	18	11	[33]
2024 (Full Year Est.)	50.47	275	18.35	N/A	[2]

Note: Statistics may vary across different sources due to different methodologies and time frames. This table integrates data from multiple sources to reflect the overall trend.

- **Impact on Biotech Companies:** The retreat of capital poses an existential threat to cash-strapped biotech companies. Many have been forced to adopt contractionary strategies, including culling non-core pipelines, downsizing staff, strictly controlling R&D expenditures, and focusing resources on late-stage projects with the highest potential for short-term value generation [32]. The old "cash-burning" model of supporting multiple early-stage, high-risk projects with continuous financing is no longer sustainable. This has compelled companies to seek new, non-dilutive sources of funding to maintain operations and growth.

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4.2 The License-out Phenomenon: Validation of Strength or Path Dependency?

It is precisely against the backdrop of the "capital winter" that license-out deals for Chinese innovative drugs have experienced explosive growth, becoming one of the most striking trends in the industry.

- **A Surge in Deal-Making:** In recent years, the number and value of deals where Chinese pharmaceutical companies license the overseas development and commercialization rights of their innovative drugs to multinational corporations (MNCs) have repeatedly set new records. In 2023, the total value of license-out deals reached $41.96 billion [28]. This momentum accelerated in 2024, with the total deal value reaching $51.9 billion and upfront payments hitting $4.1 billion [4, 34]. A landmark shift occurred in 2024 when the total upfront payments from license-out deals (approx. $3.16B - $4.1B) surpassed the total primary market financing in the innovative drug R&D sector (approx. $2.71B) for the first time, signaling that BD deals have become the most important channel for securing capital in the industry [33].
- **Landmark Deals:** Numerous high-value transactions have highlighted the appeal of China's innovative assets. Among the most notable cases: at the end of 2023, Systimmune (a subsidiary of Biokin) entered into a global strategic collaboration with Bristol Myers Squibb (BMS) for its EGFR/HER3-targeting bispecific ADC, with a total deal value of up to $8.4 billion, including a record-breaking $800 million upfront payment [28, 35]. Additionally, companies like Hansoh Pharma, Eccogene, and Duality Biologics have also secured blockbuster deals worth over $1 billion with MNCs such as GSK and AstraZeneca [35].

Table 4: Landmark License-out Deals (2023-2024)

Chinese Licensor	Multinational Licensee	Asset/Platform	Upfront Payment ($B)	Potential Total	Date	Source

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				Value ($B)		
Systimmune	Bristol Myers Squibb (BMS)	BL-B01D1 (ADC)	0.80	8.4	Dec 2023	[35]
Eccogene	AstraZeneca	ECC5004 (Small Molecule)	0.185	2.01	Nov 2023	[35]
Bliss Biopharma	Eisai	BB-1701 (ADC)	Undisclosed	2.0	Aug 2023	[35]
Hansoh Pharma	GSK	HS-20089 (ADC)	0.185	1.71	Dec 2023	[35]
Duality Biologics	BioNTech	DB-1303; DB-1311 (ADC)	0.17	1.67	Apr 2023	[35]

- **A Dual Interpretation—Validation of Strength and Underlying Vulnerability:**
  - **Validation of Strength:** Undoubtedly, the willingness of MNCs to pay high upfront and milestone payments for early-stage assets from China (many deals occur at the preclinical or Phase I stage) is a strong endorsement of the quality and source innovation capabilities of Chinese R&D [36, 37]. Especially in hot technology fields like ADCs and bispecific antibodies, Chinese companies have demonstrated global competitiveness [28, 38].
  - **Underlying Vulnerability:** However, this trend also exposes the weaknesses of China's pharmaceutical industry. Chen Qiyu, co-CEO of Fosun International, bluntly stated that this reflects the industry's dilemma: the overseas rights to innovative achievements are constantly being acquired by MNCs [28]. The fundamental reason is that the vast majority of Chinese biotech companies still lack the capability and financial resources to independently conduct large-scale, multi-regional, high-cost Phase III clinical trials and build commercialization teams abroad [28, 39]. Therefore, licensing-out is often a reluctant move of "selling green shoots," rather than a proactive strategic choice. Through this approach, companies exchange the huge value potential of overseas markets for immediate survival and development capital, but they forgo the opportunity

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to become truly global pharmaceutical players and allow China's innovation ecosystem to capture only a small fraction of the entire value chain [4, 28].

Behind this series of phenomena is the combined effect of capital, policy, and market pressure. Narrowing domestic financing channels force companies to seek capital abroad, while domestic NRDL negotiations compress profit margins in a single market, making the global market value of products critically important. Licensing-out has become a multifunctional solution: it provides precious non-dilutive cash flow to survive the "capital winter," validates asset value through the platform of MNCs, shares R&D risks, and locks in overseas market returns in advance. This is a highly rational strategic adaptation, but its long-term implications warrant deep reflection.

4.3 Charting a Global Course: The Arduous Path to FDA/EMA Approval

Besides licensing-out, another more challenging and long-term valuable globalization path is to independently complete overseas clinical development, obtain approval from the US FDA or European EMA, and conduct autonomous commercialization.

- **The Ultimate Goal and Success Stories:** This is the necessary path to becoming a truly global pharmaceutical company. In recent years, a few Chinese pharmaceutical companies have made breakthroughs on this difficult road. BeiGene's BTK inhibitor Brukinsa and Legend Biotech's CAR-T therapy Carvykti (in collaboration with Johnson & Johnson) have successfully entered European and American markets and achieved commercial success. In addition, Henlius's trastuzumab biosimilar and Bio-Thera's ustekinumab biosimilar STARJEMZA have also received approval from the EU or FDA, accumulating valuable overseas registration experience [40, 41].
- **The Overarching Challenges:** The barriers to this path are extremely high, testing a company's comprehensive capabilities in all aspects [39].

1. **Clinical Trial Design:** Must meet the stringent standards of overseas

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regulatory agencies. For example, clinical trials need to enroll subjects that reflect the diversity of the target market population (including different ethnic groups); dose selection must follow the FDA's "Project Optimus" to fully explore and determine the optimal dose, rather than directly using the maximum tolerated dose [42].

2. **Regulatory Communication Skills:** Requires the ability to communicate efficiently and professionally with agencies like the FDA and EMA, with a deep understanding of their regulatory logic and review preferences.
3. **Capital Strength and Commercialization Capability:** Independently conducting global, multi-center Phase III clinical trials is immensely expensive, often costing hundreds of millions of dollars. After approval, it is necessary to build market access, pricing, marketing, and sales teams from scratch, which is an insurmountable obstacle for most Chinese companies.

In summary, the globalization journey of China's innovative drugs is presenting a clear "dual-track model." The first track is "licensing-out," a path with relatively low barriers and numerous participants, where the core role is to be an "R&D-end" supplier in the global innovation chain. The second track is "independent global expansion," a high-risk, high-investment, high-return path that currently only a few well-funded and comprehensively capable leading companies can pursue. In the coming years, the industry's stratification will continue to intensify along these two tracks. The vast majority of biotechs will likely still rely on the first track for survival and development. Whether more companies can successfully embark on the second track and grow into homegrown multinational giants like Geely and BYD in the auto industry will be the key signpost of China's transformation from a major pharmaceutical country to a pharmaceutical powerhouse [28].

Part V: The Intellectual Property Cornerstone: Building an Increasingly Solid Legal Framework for Innovation

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The intellectual property (IP) system is the legal foundation upon which the innovative drug industry survives and develops. A strong, predictable IP protection environment is the fundamental guarantee that incentivizes companies to undertake high-risk, long-cycle R&D investments. In recent years, China has made significant strides in improving its drug IP protection framework, but challenges and gaps remain.

5.1 Analysis of the Patent Landscape

China's patent application numbers are vast, and their structure is gradually shifting from a focus on quantity to quality, especially in the pharmaceutical field.

- **Application and Grant Trends:** China is the country with the largest number of patent applications globally [43]. In 2023, China granted 921,000 invention patents [44]. In the pharmaceutical sector, the number of invention patent applications and grants has continued to grow, indicating vibrant innovation activity [45, 46]. However, the latest data shows a year-on-year decline in pharmaceutical patent grants in the first quarter of 2025, which may be related to the macroeconomic environment, adjustments in corporate R&D investment strategies, or stricter patent examination standards [47].
- **Distribution by Technology Field:** In terms of the technological composition of patents, recently granted pharmaceutical patents are predominantly for drug delivery devices (such as smart injection pumps, microneedle patches), drug preparation methods, and diagnostic technologies [47]. In contrast, the number of patents involving novel drug targets, drug crystal forms, and new uses—which represent more fundamental, source-level innovations—is relatively small. This, to some extent, reflects the characteristics of current R&D activities: highly active in applied technologies and incremental innovations, but with room for improvement in more groundbreaking basic scientific discoveries. At the corporate level, traditional large pharmaceutical companies like Hengrui Medicine, Tasly, and Kelun Pharmaceutical are the leaders in patent applications, possessing deep patent

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portfolios [48, 49].

- **The Trade-off between Value and Quantity:** Despite the huge number of patent applications, translating "patent quantity" into "high-value patent portfolios" that can withstand the tests of the international market and legal challenges remains a core challenge for Chinese pharmaceutical companies. Analysis indicates that compared to mature markets like the US, the proportion of high-value patents in China (i.e., patents with broad protection scope, difficult to circumvent, and capable of supporting the commercial value of core products) is still low [50].

5.2 The New Moat: Drug Patent Linkage and Patent Term Extension (PTE)

To align with mainstream international IP protection levels and provide stronger protection for innovative drugs, China officially introduced two key systems when it amended the Patent Law for the fourth time in 2020: drug patent linkage and patent term extension (PTE), which came into effect on June 1, 2021 [51, 52]. These two systems aim to balance the interests of innovative and generic drug companies and are considered milestones in the maturation of China's drug IP protection system.

- **Drug Patent Linkage System:** This system links drug review and approval with patent status. When a generic drug company submits a marketing application, it must declare that it does not infringe the valid patents of the relevant innovative drug. If the innovative drug company (the patentee) believes there is a risk of infringement, it can file a lawsuit or request an administrative ruling from the court or the China National Intellectual Property Administration (CNIPA), triggering a "stay" of the review and approval process for up to 9 months. This provides patentees with an opportunity to resolve patent disputes before the generic drug is launched, avoiding potentially huge losses after market entry.
- **Patent Term Extension (PTE) System:** This system aims to compensate for the patent protection time consumed by the drug review and approval process, thereby extending the market exclusivity period of innovative drugs.

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- **Core Calculation Formula:** Patent Term Compensation = (China Drug Approval Date - Patent Application Date) - 5 years [52, 53].
- **Key Limiting Conditions:**

1. **Maximum Compensation of 5 Years:** The compensation period itself cannot exceed 5 years.
2. **Total Post-Approval Protection Not to Exceed 14 Years:** Even with compensation, the total effective patent term after the new drug is approved for marketing cannot exceed 14 years.
3. **Narrow Scope of Application:** Compensation primarily applies to Class 1 innovative drugs ("global new" drugs). Many improved new drugs (such as Class 2.2 chemical drugs) that are launched for the first time in China but have similar products approved overseas are excluded [52].
4. **"One Drug, One Patent; One Patent, One Drug":** A single drug can only receive term compensation for one patent; a single patent can only be compensated for one drug [52, 54].

- **International Comparison and System Limitations:** Compared to the PTE systems in major global pharmaceutical markets, China's system, while aligned in framework, is stricter and more conservative in its specific implementation details.

Table 5: Comparison of Patent Term Extension (PTE) Systems in Major Global Markets

Feature	China	USA	EU	Japan
Eligible Drug Types	Mainly Class 1 innovative drugs (global new)	Innovative drugs, some improved new drugs	Innovative drugs	Innovative drugs, improved new drugs
Compensation Calculation	(Approval Date - Filing Date) - 5 years	1/2 Clinical Time + Review Time	(First Approval Date - Filing Date) - 5 years	Approval Date - (Start of Trials or

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				Patent Grant Date, whichever is later)
Max Compensation Term	5 years	5 years	5 years	5 years
Max Total Post-Approval Patent Term	14 years	14 years	15 years	No explicit limit
Patents Compensated per Drug	1	1	1	Multiple
Drugs Compensated per Patent	1	1	1	Multiple

Source: Compiled based on information from [52, 53, 54]

As the table shows, China's PTE system is stricter than other major markets, especially Japan, on multiple dimensions. For example, Japan allows compensation for improved new drugs and permits "one drug, multiple patents" and "one patent, multiple drugs" compensation, which greatly incentivizes continuous, incremental innovation. China's stringent regulations reflect a deliberate balance by policymakers between "encouraging breakthrough innovation" and "accelerating generic drug accessibility to reduce healthcare burdens."

Overall, China's IP framework is largely complete, providing "good, but not top-tier" protection for innovation. It has successfully enhanced protection for innovators, but its limitations also clearly indicate that the policy scales are not entirely tipped in favor of innovators. This institutional design, on one hand, provides a "moat" for domestic innovative drug companies against premature generic competition. On the other hand, by limiting the breadth and strength of the protective umbrella, it reserves space for subsequent generic competition. For global pharmaceutical companies and investors, understanding these nuances of China's IP system is crucial for accurately assessing the long-term value of assets in China.

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Part VI: Strategic Outlook and Forward-Looking Forecast (2025-2030)

Based on the preceding analysis, China's innovative drug industry stands at a crossroads shaped by policy, capital, and innovation capabilities. Its development over the next five years will depend on the interplay of these forces and the industry's ability to successfully navigate current core challenges and seize new growth opportunities.

6.1 The Interplay of Key Forces: A Triple Dilemma of Policy, Capital, and Innovation

In the coming years, the development of China's innovative drug industry will continue to be defined by the interaction of three core forces:

1. **The Normalization of the "Policy Squeeze":** On one hand, full-chain support for innovation and accelerated review and approval; on the other, deepening healthcare cost control through strict price management via NRDL and VBP mechanisms. This "carrot and stick" policy mix will become the long-term "new normal," continuously exerting dual pressure on companies to innovate and reduce costs.
2. **The Evolution of the "Innovation Paradox":** The "involution" phenomenon in R&D pipelines is unlikely to be fundamentally reversed in the short term. However, as the capital markets and regulatory bodies converge on the value of "true innovation," and as commercial returns from homogeneous competition continue to decline, it is expected to force companies to gradually differentiate from "red ocean" targets and seek more distinctive R&D paths.
3. **The Deep Integration of Capital and Globalization:** The "capital winter" and the boom in license-out deals have deeply tied the fate of Chinese innovative drug companies to the strategic needs of global capital markets and multinational corporations. While this path provides a lifeline, it may also solidify China's role as a global "R&D outsourcing base."

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These three forces constitute a complex "triple dilemma": companies must pursue truly valuable innovations that can escape homogeneous competition, using limited capital in a stringent policy environment, and successfully achieve global commercialization. How to resolve this dilemma is the ultimate test for all participants.

6.2 Future Growth Engines and Potential Risks

Looking ahead, the industry's growth will be ignited by new drivers, but the path forward is also fraught with potential risks.

- **Future Growth Engines:**
    - **Beyond Oncology, Embracing Diversification:** While oncology remains an R&D stronghold, future significant growth will emerge in currently relative "blue ocean" areas. In particular, metabolic diseases (e.g., the obesity and diabetes market led by GLP-1 agonists), autoimmune diseases, and neurodegenerative diseases, which have vast patient populations and huge unmet needs, are poised to become the next "golden tracks" [7, 22].
    - **Mastery of Cutting-Edge Technology Platforms:** Industry leadership will no longer depend merely on fast-following a specific target, but more on mastering and applying next-generation disruptive technology platforms. Cell and gene therapy (CGT), novel antibody-drug conjugates (ADCs), radioligand therapy (RLT), small nucleic acid drugs (like siRNA), and AI-empowered drug discovery will be the cradles for the next generation of blockbuster drugs [4, 29, 55, 56, 57].
    - **Realizing "True Globalization":** The few companies that can successfully navigate the "independent global expansion" track will, by building global clinical and commercialization capabilities, completely break free from dependence on a single market and capture the full value of the global market. They will become the "national champions" of China's pharmaceutical industry

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and lead the upgrade of the entire ecosystem.

- **Integration of AI and Digitalization:** The application of artificial intelligence in drug target discovery, compound screening, and clinical trial design will significantly improve R&D efficiency and reduce costs [29, 58, 59]. Emerging fields like digital therapeutics (DTx) will also open up new growth curves.

- **Potential Risks and Pitfalls:**

  - **Vicious Cycle of "Involution":** If homogeneous competition is not effectively curbed, it could lead to a continuous decline in the industry's profit margins, creating a situation where "bad money drives out good" and ultimately stifling companies' willingness and ability to conduct high-risk, long-cycle source innovation.
  - **Policy Unpredictability:** Healthcare reimbursement policy is the biggest variable affecting industry development. Any sudden or drastic adjustments to NRDL negotiation rules, the scope of VBP, or pricing mechanisms could have a huge impact on corporate valuations and strategic planning.
  - **Geopolitical Clouds:** Increasingly complex international relations, especially tensions between China and the US, could bring uncertainty to cross-border technology cooperation, capital flows, talent exchange, and market access, posing potential threats to companies' globalization strategies.
  - **Falling into the "Middle-Innovation Trap":** This is the industry's biggest long-term risk—being content to be an efficient "fast follower" and a link in the global R&D chain, without ever achieving a fundamental leap to source innovation (First-in-Class), ultimately finding itself in an awkward "not high enough, not low enough" position in the global industrial landscape.

6.3 Strategic Recommendations for Key Stakeholders

Facing a future of coexisting opportunities and challenges, different players need to

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adopt differentiated strategies for survival and development.

- **For Innovative Biotech Companies (Biotech):**
    - **Focus on Differentiation, Reject Involution:** Must invest limited resources in projects with real clinical differentiation value. Prioritize true unmet clinical needs, pursue FIC or BIC with clear clinical advantages, and proactively avoid overcrowded targets.
    - **Embrace "Smart BD":** Treat licensing-out as a strategic tool, not just a simple "sell-off." Strive for co-development and co-commercialization rights in negotiations, or retain rights for specific regions (like Greater China), using this as a springboard to learn and accumulate globalization experience.
    - **Prioritize Capital Efficiency:** Against the backdrop of the "capital winter," maintain lean operations, conduct rigorous prioritization and ruthless "survival of the fittest" for the R&D pipeline, ensuring every penny is spent wisely.
- **For Large, Mature Pharmaceutical Companies:**
    - **Leverage the "Emptying the Cage" Dividend:** Make full use of the cash flow from existing products to actively acquire high-quality external innovative assets through M&A and license-in deals, thereby rapidly iterating and enriching their own R&D pipelines.
    - **Act as "Globalization Navigators":** Leverage their advantages in capital, manufacturing, registration, and commercialization to become the "partner of choice" for domestic biotechs. By building a "group fleet for going global" industrial ecosystem, they can lead more small and medium-sized enterprises to the international market, consolidating their own "chain leader" position in the process [28].
- **For Investors (Venture Capital and Secondary Market):**

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- **Shift from Speed to Quality:** Investment logic needs to shift from rewarding the "fastest runner" to rewarding the "best performer." The focus of evaluation should be on the scientific novelty, clinical differentiation potential, and global market competitiveness of projects, not just the speed of entry into a hot track.
- **Cultivate Patient Capital and a Global Perspective:** Deeply recognize that breakthrough innovation requires time and high investment. When evaluating companies, more emphasis should be placed on their long-term globalization strategy and sustainable value creation capabilities, rather than short-term domestic market performance.
- **Invest in the Source of Innovation:** Increase investment in earlier-stage, more fundamental platform technologies and new target discovery, helping the entire ecosystem to break free from the gravitational pull of "involution" at its source and providing fertile ground for the birth of truly disruptive innovations.

In conclusion, the future of China's innovative drug industry is a "triathlon" of survival and development under stringent rules. Only those companies that can strike a delicate balance between policy, capital, and innovation capabilities, and steadfastly choose the path of differentiation and globalization, will ultimately navigate the cycle and reach the shores of victory.

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