Business Strategy Analysis in the Pharmaceutical Industry: A Case Study of Kelun Pharmaceutical

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Abstract. This essay investigates a sector remodeled by institutionalized cost management, rapid modality expansion such as antibody–drug conjugates (ADCs) and cross-portfolio quality governance among distributed supply chains where companies shift from single-blockbuster bets to value-based portfolios. This essay carries out a theory-building single-case examination of Kelun, triangulating disclosed information and peer literature to process-trace how procurement price pressure, ADC commercialization demands, and multi-product compliance get mapped into portfolio, access, and operations decisions; the author adds a development timeline and a present-day operating review to ground mechanisms. Three managerial frontiers emerge with coordinated interventions: a two-speed portfolio (scale for commoditized, tendered products and differentiation for readymade/innovative assets), a sequenced ADC roll-out—biomarker-driven entry, combination-driven growth expansion, payer evidence, mature chemistry, manufacturing, and controls (CMC); and an enterprise quality-by-design (QbD)/analytics platform with risk-band suppliers and digital quality-management system (QMS); collectively they account for Kelun's transition from infusion leader to a three-pillar platform transforming price pressure into cash flow as innovation into growth optionality with compliant burden contained. In practical terms, the essay presents portable playbooks—regulatory routines, metrics to inform performance, partnering structures—for use by managers and regulators; theoretically, it contributes an integrated framework connecting cost management, modality complexity, and compliant burden at scale with testing hypotheses available for multi-case or panel types as well as procurement designs maintaining supply resilience and innovation.

Keywords: Centralized Procurement, ADC Commercialization, Multi-Product Compliance.

1. Introduction

As budgets are tighter, medical technology advances, and worry about quality risks rises, the global drug industry now increasingly depends on structured cost control, multi-modal R&D and manufacturing, and broad, resilient supply chains. As a result, instead of the old model of launching one “blockbuster” drug, the industry has moved firmly to a value-led product mix and portfolio management across markets and therapy areas around the world. This shift has created three practical management frontiers: disciplined pricing through procurement, faster commercialization of complex platforms, and compliance for many products at scale. Kelun, a Chinese drugmaker, shows this change by linking its infusion and active pharmaceutical ingredient base with new antibody–drug conjugate assets and a digital quality platform. For a long time, a leader in infusions, Kelun has moved to a three-pillar platform covering infusions/APIs, antibiotics, and innovative medicines such as ADCs and synthetic-biology assets. Kelun’s case points to a key question: how can companies turn these frontiers into a durable growth path without slowing their innovation?

Existing research has made significant discoveries regarding the three core areas summarized above. First, regarding institutionalized cost control, Li et al. conducted a difference-in-difference analysis of 102 A-share listed chemical companies, found that while the National Medical Products Administration (NCDP) promotes R&D investment, it can also discourage small and medium-sized enterprises (SMEs) with low bid-winning rates [1]. The NCDP represents an institutionalized model for lowering drug prices through a "volume-for-price" approach. Therefore, this research suggests that the current pharmaceutical industry is driving companies toward scale, innovation, and differentiation. Second, Yajaman et al. reviewing recent advances in ADCs for precision oncology,

noted that ADC efficacy is highly dependent on the drug/antibody ratio (DAR), site-specific conjugation, linker stability, and loading mechanism [2]. This suggests that current research in the pharmaceutical field has shifted from single-point "target discovery" to a multi-step engineering optimization approach. This confirms the multimodal R&D trend mentioned above. Finally, Wang et al. (2024) reviewed the current state of innovative analytical technologies in pharmaceutical production and their related regulation, finding that innovative analytical technologies (such as real-time monitoring and rapid testing) are already enabling consistent quality assurance across multiple production nodes [3]. Furthermore, data exchange enabled by cloud platforms offers an optimistic outlook for future global regulation [3]. This suggests that key tools are already in place to support the trend toward distributed production and supply chain management.

This essay aims to use click-through logic to conduct a model-building case study, focusing on Kelun Pharmaceuticals. The study aims to analyze the challenges facing the global pharmaceutical industry and propose corresponding solutions. This essay will conduct an in-depth analysis of relevant information obtained from official channels, including Kelun Pharmaceuticals' ESG report, to chart its development history and operational priorities. Based on this foundation and informed by macroeconomic trends in the industry, the article will identify the challenges it faces and propose solutions.The study methodology contributes to the construction of an integrated framework to link cost control, modal complexity, and scale compliance and provides valuable lessons for sector development strategy.

2. Case Description

Kelun's expansion follows its evolution from a leading infusion company into a three-pillar platform business spanning "infusion + antibiotics + innovative drugs/ADCs + synthetic biology." As shown in Table 1, the company was founded in 1996 and established a high-capacity Good Manufacturing Practice (GMP) infusion base in 1999—a very efficient purchase platform—then rebuilt in 2004, finishing upstream integration [4]. Its 2011 Shenzhen IPO funded its diversified expansion [4]. Between 2020 and 2019, SKB264 entered global trials, where it transformed into a sophisticated model [4]. In the year 2021, approval of its initial powder-liquid dual-chamber formulation took effect, substantially improving its abilities in terms of ready-to-use safety as well as Quality by Design (QbD) implementation [4]. By 2023, the three-pillar platform had balanced pricing pressure and supply risk [4]. In 2024, the approvals for the TROP2 antibody-drug conjugate (ADC) and the synthetic biology UDCA API marked the simultaneous advancement of innovation and production modernization [4].

Table 1. Kelun's development process

Year	Selected milestones
1996	Founded as Sichuan Kelun Large Pharmaceutical Factory (origin of Kelun).
1999	Built a large infusion base and passed provincial GMP inspection, establishing high-volume IV capacity.
2004	Reorganized into a joint-stock company; nationwide infusion footprint expanded and upstream packaging integrated.
2011	Listed on the Shenzhen Stock Exchange (SZ002422), enabling capital-market financing for scale and diversification.
2019-2020	SKB264 (TROP2 ADC; later MK-2870) received clinical acceptance/INDs, marking a pivot to complex modalities.
2021	First powder–liquid dual-chamber product (ceftazidime + 5% glucose) approved, advancing ready-to-mix safety/compliance.

2023	Kelun Biotech listed on HKEX; tri-pillar platform formed (Kelun Pharma, Chuan Ning Bio, Kelun Biotech).
2024	China approval of the TROP2 ADC (sac-TMT/MK-2870); UDCA API approved via synthetic-biology route; platform scale consolidated.

Source: https://kelun.com/intro/142.html

Kelun's operations currently demonstrate resilient profitability and a strong commitment to transformation. By 2024, the group aims to achieve revenue of RMB 218.1 billion (up 1.7%), net profit of RMB 2.94 billion (up 19.5%), R&D investment of RMB 2.17 billion (9.95% of sales), and a R&D staff of 2,855 [5]. This growth is primarily driven by the expansion and cost-effectiveness of its antibiotic intermediates/API business; an upgraded infusion set portfolio (multi-lumen/dual-lumen); the domestic approval of two innovative drugs—a sac-TMT (TROP2-ADC) and a PD-L1 antibody—as well as certification of its ursodeoxycholic acid API (UDCA); and progress in its digital/artificial intelligence quality initiatives [5]. At the subsidiary level, as shown in the Table 2, Kelun Biotech achieved revenue of RMB 1.93 billion (a 25.5% increase), saw a significant increase in gross profit, narrowed losses (-RMB 267 million) [6]. Kelun Biotech has also received recognition from the capital market (including inclusion in the Hang Seng Index and placements) [6].

Table 2. Kelun-Biotech's 2024 financial results

Item	Note	2024	2023
Revenue		1933045	1540493
Cost of sales	3	-659388	-781308
Gross profit		1273657	759185
Other net income		139755	89809
Selling and distribution expenses		-182717	-19534
Administrative expenses	4	-163310	-181877
Research and development expenses		-1206134	-1030966
Operating loss		-138749	-383383
Finance costs	5(a)	-3796	-84309
Loss before tax	5	-142545	-467692
Income tax	6(a)	-124221	-106442
Loss attributable to owners of the Company for the year		-266766	-574134
Loss per share — basic and diluted (RMB)	10	-1.2	-2.84

source: https://kelun-biotech.com

Overall, Kelun's commercialization has begun, but is still in its early stages and partially relies on partners outside of China. Overall, Kelun has moved beyond proof-of-concept into early commercialization: the group is anchored by a rigorous quality system and a pipeline that now spans multiple modalities, including ADCs. Yet progress outside China still leans on partners, and three operating frictions shape the road ahead: first, procurement-driven pricing pressure on legacy; second, the sequencing of market access, evidence, and mass-production learning curves for ADCs; and third, the rising complexity of cross-portfolio regulatory compliance at scale. The next section unpacks these three issues and why they matter for a two-speed portfolio and platform build-out.

3. Problem Analysis

3.1. Procurement-driven Price Compression

Under institutionalized centralized procurement, Kelun’s legacy infusion and chemical-generic base is exposed to durable ASP erosion. Company disclosures explicitly acknowledge this environment in two ways. First, they document wide participation and deeper-than-average cuts in national volume procurement—59 varieties across 83 specifications selected, with average price reductions larger than the program average—signaling that bid success comes with structurally lower unit prices [5]. Second, they enumerate concrete post-negotiation declines, e.g., Sugammadex

reimbursement falling from RMB1,080/vial to RMB136 (-87.4%) and parenteral nutrition bags dropping to just over RMB70 after the 5th round (about -75%) [5]. Moreover, Kelun states it must list eligible products at centralized-procurement prices across channels, compressing any downstream spread [5]. This combination explains the dilemma: high tender hit-rates expand volume and contract portfolios but do not automatically translate into contribution margin, thereby constraining cash generation for reinvestment in the three-pillar architecture.

3.2. ADC Commercialization Ramp

With sac-TMT only receiving China approval in 2024, Kelun's ADC business remains at an early commercialization stage, which implies limited near-term earnings support. A 2025 study by Zhou et al. showed that the launch of ADCs often faces challenges with manufacturing scale-up and CMC reproducibility, complex pharmacokinetic and toxicity profiles, and higher commodity costs that can delay break-even [7]. These factors undoubtedly exacerbate the burden on Kelun, a new entrant. Kelun's reliance on overseas collaborations further exacerbates its uncertainty. Specifically, Kelun-Biotech has granted Merck sac-TMT an exclusive license to manage its programs outside of Greater China. Merck is currently responsible for the global execution of 12 Phase III programs, covering areas such as triple-negative breast cancer and non-small cell lung cancer [6]. While this collaboration significantly expands Kelun's geographic reach, it also places the company's control over related decisions at high risk. For example, the cadence of study results and the order of filings will be influenced by Merck's portfolio decisions for these Phase III studies. For this reason, even if Koren's existing business progress has made tangible progress, the pressure of uncertain short-term profit conversion cannot be ignored.

3.3. Multi-product Quality and Compliance at Scale

As Kelun expanded from infusions to APIs, synthetic biology, and biologics, it significantly strengthened its GMP, data integrity, and change control efforts across sites and suppliers. The company disclosed that at the end of the period, all production sites had passed GMP, with 13 certified by ISO9001, representing 40.63% of its manufacturing operations. This demonstrates proactive quality management but also requires a higher investment in recordkeeping [5]. On the supply side, 420 supplier audits (320 on-site and 100 written) were completed by 2024, covering strategic, bottleneck, and high-risk categories, representing a completion rate of 151% of the planned total [5]. The problem is that these high standards themselves create operational friction—heavier data review before batch release, more frequent cross-site consistency verification, and more complex ongoing process characterization for new modalities like ADCs (e.g., drug loading ratio and linker stability). This increases compliance costs and response times, potentially delaying scale-up and iteration. An industry review also notes that while QbD can reduce volatility, it places high demands on data infrastructure and cross-departmental collaboration, and early implementation often presents resource bottlenecks [8]. This requires Kelun to maintain an ideal low accident record through audits and systems, while also striking a cost-effective balance between audit intensity and investment in a digital QMS. Otherwise, multimodal parallel development could make the quality system a hidden constraint on production expansion and technology transfer.

4. Suggestions

4.1. Adopting Dual-speed Product Portfolio Strategy

Following the observation by Li et al., centralized procurement saves not only costs but also shifts market share [1]. Kelun and pharmaceuticals dealing with a comparable challenge respond to procurement-driven price compression by adopting a dual-speed product portfolio. For Kelun, its core infusion product is a fast track and its innovative products such as ADCs a slow track. For Kelun, its core infusion product is a fast track and its innovative products such as ADCs a slow track. Kelun accordingly develops two strategies according to their varying decision-making periods and pricing

mechanisms to avoid mutual drag from centralized management. Such a strategy is an example whose macro-level orientation is more relevant to trends nowadays. It is also a fundamental step for the pharmaceutical industry to move on from conventional single-product lines. Moreover, with increasing institutionalization of cost controls, organizations should also institutionalize bidding disciplines such as indexing input costs or setting thresholds for total return on investment. Evidence from China's NVBP shows why a dual-speed design is necessary: winning suppliers are guaranteed 60–70% of prior-year volume, a mechanism that turns a company's mature products into low-price, high-volume businesses, while innovative products are inherently uncertain, requiring companies to control the innovation "slow lane" while protecting the cash flow "fast lane." [9]. This mechanism resonates logically with the strategy presented in this essay.

4.2. Stage-Gated ADC Commercialization Strategy

Based on Yajaman et al., ADC value depends on choices like engineering design and the order in which evidence is built, not just efficacy [2]. For example, a TROP2-ADC was first tested in lung-cancer patients with high TROP2 expression, then PD-1 combinations were tried to widen indications to other tumor types. Efficacy and economic data were simultaneously collected on a planned basis to facilitate hospitalization, reimbursement, and pricing [2]. This means that companies need to selectively decide on the launch and scale-up path for ADCs. Specifically, they should start with patients most likely to benefit, using biomarker-matched testing to identify those with the most accurate biomarkers, thereby ensuring the clearest possible efficacy and safety profile for the drug in this population. From this foundation, they can gradually expand the scope of application. Furthermore, they should prepare the evidence that payers are interested in in advance to facilitate reimbursement and pricing negotiations. Furthermore, given the current global presence, partnership governance should be established in each region.

4.3. Enterprise QbD & Digital QMS

As Wang et al. demonstrate, existing testing and digitalization tools can bring broad benefits to pharmaceutical product management [3]. Companies should implement enterprise QbD programs covering small molecules, synthetic biology APIs, infusions, and biologics production lines: PAT-based monitoring with real-time release where appropriate; a digital quality management system with data integrity by design; and a cross-site technology transfer manual with predefined change control channels. Use failure mode modeling to categorize suppliers by risk level; conduct qualification reviews of parallel suppliers to avoid the risk of a single supplier; and use leading indicators (first-time success, Corrective and Preventive Action (CAPA) speed, Process Performance Qualification (PPQ) success rate, variability index) for governance. These steps fit QbD's control strategy and improvement cycle—tying Critical Material Attributes to Critical Quality Attributes, enabling Real-Time Release Testing, and easing efficient post-approval change control [10].

5. Conclusion

Through thorough analysis, this article integrates three strategies: dual-tier product lines, ADC stratification strategy, and implementation of QbD. The strategies are connected in two ways: First, by adjusting procurement strategies, Kelun is able to target price and quantity to ensure that they maintain sufficient cash flow. The strategies are connected in a few ways: First, by adjusting procurement strategies, Kelun can focus on both price and quantity to make sure they have enough cash flow. As ADC research and clinical trials progress, more growth opportunities will open up for the company. By using QbD and data analysis, the company can control both costs and quality, set clear standards, and scale up without losing control. However, these strategies also depend on factors like capital structure, supplier risks, and the company's ability to enter different markets, which affect how easily these strategies can be applied elsewhere. One weakness is heavy use of public sources and a lack of firsthand data, which could lower the study's strength. Furthermore, the conclusions

drawn from a single Chinese case are limited in their applicability. Therefore, future work should focus on collecting real-world evidence and incorporating multi-case panels to establish more robust and reliable causal relationships.

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