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Beyond borders 2025: the top five considerations on the road to success in cross-border life sciences M&A

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Strategic shifts: from full M&A to licensing and co-development models

Traditional M&A remains important, but companies are increasingly favouring licensing, joint ventures and co-development deals to manage risk and retain flexibility.[1] These alternative structures are especially valuable when navigating the uncertainty of early-stage science or unfamiliar regulatory environments.

A prime example is Astellas Pharma's $1.54bn deal with Evopoint Biosciences in May 2025 for an antibody–drug conjugate (ADC) targeting CLDN18.2. Instead of a full acquisition, Astellas opted for a strategic collaboration structure through an exclusive licence agreement with upfront, near-term and other phased payments tied to development and commercialisation, in addition to royalties on ADC's net sales if it receives regulatory approval.[2] This structure enhances Astellas' access to an emerging cancer therapy and strategically enhances its oncology product pipeline.

Similarly, Novo Nordisk's $2bn licensing agreement with The United Laboratories International Holdings for a Phase 2 GLP-1/GIP/glucagon receptor agonist in early-stage development for obesity and type 2 diabetes, reflects a pivot towards securing innovation from overseas developers.[3] This strategy broadens Novo Nordisk's global footprint and supports its chronic disease pipeline.

Such structures empower growth for biotech innovators in emerging markets, while allowing large pharma to spread the development costs across multiple years, mitigating risk through milestone-based payments and regulatory triggers.

Strengthening the IP framework in a cross-border context

Intellectual property (IP) remains the cornerstone of value in life sciences deals. However, cross-border transactions demand heightened diligence around enforceability, jurisdictional coverage and IP security.

For example, in 2025, Pfizer secured a $6.05bn licensing deal with 3SBio for a bispecific antibody targeting PD-1 and VEGF, for non-small cell lung cancer, gynaecological tumours and metastatic colorectal cancer, underscoring the growing importance of dual-mechanism oncology assets.[4] The transaction also reflects Pfizer's trust in 3SBio's patent position and product capabilities in China, indicating improved perceptions of IP strength in emerging markets.

Nonetheless, differences in IP laws, data exclusivity and enforcement regimes mean that deal parties must work with counsel experienced in global IP strategy and its impacts on product development. This is particularly important for preclinical, early clinical phase assets, where the strength of data packages can be improved by robust IP strategies that make or break a transaction.

Navigating regulatory hurdles and product approval pathways

Cross-border deals are rarely just about science and IP, they are equally about regulatory strategy. Understanding how a product will move through differing and often complex regulatory regimes involving the United States. Food and Drug Administration (FDA), China's National Medical Products Administration (NMPA) or the European Medicines Agency (EMA) is central to deal valuation and timing.

Consider Merck & Co.'s $1.97bn agreement with Hengrui Pharma for a Phase 2 Lipoprotein(a) inhibitor, currently subject to clinical trials in China.[5] The decision to licence a Chinese-developed cardiovascular candidate signals Merck's confidence in its ability to partner with Hengrui in order to meet global regulatory product approval standards, including those required by the FDA. This marks a shift from previous decades when global players may have been more wary of development opportunities outside of the US, let alone in China, marking a departure from earlier industry scepticism.

Similarly, Regeneron's $2.01bn licensing agreement with Hansoh Pharma for HS-20094, a dual GLP-1/GIP receptor agonist for use as an obesity and metabolic disease therapy, further demonstrates the trend towards selecting partners outside of the US that have products in development with profiles similar to current FDA-approved products.[6]

Successful partnerships and licensing agreements hinge on robust regulatory due diligence, encompassing inspection histories, clinical trial design alignment and the relevant

chemistry/manufacturing/control (CMC) capabilities, key factors for regulatory approval and commercialisation success.

Harnessing data and AI in due diligence and asset valuation

Artificial intelligence (AI) is increasingly shaping not only the drugs being developed, but also how deals are being executed and the products being brought to the market. From early discovery to patient stratification in clinical trials, AI is transforming value assessment and risk analysis.

In July 2025, GSK entered into a $12.5bn collaboration with Hengrui Pharma to co-develop up to 12 innovative medicines and early-stage assets spanning respiratory, immunology, inflammation and oncology platforms.[7] Hengrui's foundation for innovation includes an AI molecular design platform, illustrating how AI-enabled discovery can accelerate research and development (R&D) and potentially enhance deal attractiveness.

On the transaction side, AI is being used for smart due diligence to increase efficiency. Machine learning models now analyse data rooms, prior IP claims and clinical data in real time, compressing weeks of manual review into hours. However, AI's growing role also introduces considerations around data rights, data residency and ethical data usage, especially in jurisdictions with strict data localisation laws. These issues must be addressed in regard to cross-border structuring and post-deal integration.

Partnership strategy and long-term value realisation

While much focus is placed on deal execution, savvy acquirers and licensors increasingly prioritise long-term partnership opportunities and value realisation post-deal. This approach includes the consideration of commercialisation pathways, regional collaboration and shared product success strategies.

A standout example in this regard is Vor Biopharma's $4.125bn global licence agreement with RemeGen for telitacicept, a late-stage fusion protein that targets immune pathways involved in autoimmune diseases. Telitacicept is already approved in China for the treatment of lupus erythematosus (SLE) and rheumatoid arthritis.[8] RemeGen is conducting a Phase 3 clinical trial with patients in the US, Europe and South America to support future regulatory approval processes in the US and Europe. The agreement's milestone-based structure, coupled with market confidence reflected in Vor's rising share price, underscores investor appetite for diversified, globally oriented alliances.

Likewise, Expedition Therapeutics' recent $645m agreement with Fosun Pharma for a small-molecule DPP-1 inhibitor demonstrates how US biotech leverages China's capital and uses cross-border

partnerships for market access purposes and eventual commercialisation pathways in Asia or Europe.[9]

Robust partnership frameworks enable smoother transitions, clearer returns on investment (ROI) and stronger global product lifecycle management, hallmarks of sustainable cross-border success.

Conclusion: adapting to a borderless future

As global dynamics reshape the pharmaceutical landscape, cross-border M&A strategies continue to evolve. The shift from traditional acquisitions to licensing, co-development, and data-driven alliances reflects a new paradigm that involves the prioritisation of agility, strategic alignment and shared development risk.

By focusing on five key considerations, namely deal structuring, IP protection, regulatory alignment, AI/data strategy and long-term partnership planning, the life sciences sector can unlock the full potential of cross-border collaboration.

For legal and business leaders, success in this environment will depend on a nimble, globally minded approach to dealmaking—one that embraces innovation without borders.

"Beyond borders 2025: the top five considerations on the road to success in cross-border life sciences M&A," *International Bar Association*, December 4, 2025

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