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Published by Financier Worldwide Ltd

SPECIAL REPORT ARTICLE REPRINT November 2023

Strategic considerations in life sciences partnering

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Partnering transactions in the life sciences space play a critical role in fuelling innovation in pharmaceutical and biotechnology research and development (R&D) and creating value for stakeholders across the life sciences ecosystem.

Notwithstanding the challenges posed by recent market conditions, companies need to build or expand their pipelines. Accordingly, there is demand for new assets and technologies that have the potential to address unmet needs of patients across a variety of indications.

At the same time, partnering transactions provide research-stage companies with a non-dilutive financing alternative in which they can monetise their pipeline assets and technology.

Partnering transactions are never 'one size fits all'. Instead, they are complex, bespoke arrangements that can take a variety of forms. Moreover, they require multidisciplinary coordination among experts in legal, finance, R&D, regulatory, chemistry, manufacturing and controls (CMC), alliance management, business development and other functional areas.

As the name suggests, partnering requires deep collaboration between companies, often to develop, seek regulatory approval for and ultimately commercialise novel pharmaceutical and biotechnology products, or it may be directed to developing and exploiting platform and other enabling technologies.

In contrast to M&A transactions, which are often episodic and involve one company acquiring ownership of another company or its assets, partnering transactions are effectively contractual joint ventures that involve long-term commercial relationships that exist over the lifecycle of a product or series of products. This affects the negotiation dynamic given one must look far into the future and consider how the parties will work with each other for years after closing.

What makes a partnering transaction attractive is that each party expects to benefit from expertise or intellectual property (IP) that the other party contributes to the joint venture. For example, one party may have expertise in early-stage development of a novel product, whereas the other party may have expertise in carrying forward that product into late-stage development and commercialising it on a global basis or in a specific territory.

Common structures include licensing arrangements, co-development arrangements, co-commercialisation arrangements, option arrangements

or hybrid arrangements that include elements from different types of structures. These arrangements may also include additional commercial or regulatory contracts, such as manufacturing and supply, pharmacovigilance or distribution agreements.

Ultimately, the structure adopted by the parties will depend on the scope of the joint venture, the allocation of development and commercialisation responsibilities to each party, and the commercial goals and strategic objectives of each party.

Given that these arrangements are highly bespoke and intended to 'live and breathe' over many years as they are designed to govern the development and commercialisation of products over their lifecycle, they are often vulnerable to disputes and litigation. Therefore, it is critical that parties legislate terms clearly, including with respect to dispute resolution mechanisms, so they can be understood by legal and operational teams long after the transaction has closed, thereby reducing the risk of conflicting interpretations of contractual language and the potential for litigation.

Moreover, while partnering arrangements contain provisions that may be relatively standard and for which there is an understood market practice, there are often many other provisions that are unique to the transaction being negotiated and thus require creativity and flexibility for successful deal execution.

In addition to a careful focus on transaction-specific issues, each party must adopt a wider perspective and consider the potential impact a transaction can have on its broader business and strategic objectives, such as whether any transaction terms could implicate other pipeline assets or its ability to execute future transactions.

Ultimately, the specific considerations that a party will confront will vary depending on the nature of the transaction. To illustrate how some relatively common considerations may be addressed in a transaction, below we offer perspectives from a hypothetical licensor, such as a product innovator, and licensee, such as a commercial partner.

In a partnering arrangement, the licensor's primary objectives are typically analogous to those of a seller in an M&A transaction, namely, to maximise near-term value by selecting a strategic partner that will successfully monetise the licensed products. However, when a licensor is determining how to approach an out-licensing arrangement, it must avoid thinking in a vacuum and invest time upfront to consider how the transaction will affect its long-term strategy. For example, if the licensor could be a future acquisition target, will seek additional financing, or may become a public company, it is important to consider how any future acquirer, financing source or the public markets will view its partnering arrangements.

One key element of constructing a long term partnering strategy is for the licensor to conduct a mapping exercise. Particularly for licensors that control pipelines comprised of advanced medicines or platform technologies that have multiple applications, such as for multiple disease indications or biological targets, they must consider how they will allocate rights to their medicines and technologies among various potential partners.

It is essential that the rights are clearly demarcated so that the line as to where one partnership ends and another begins is clear, whether this is achieved by reference to certain IP or technology, specific product candidates or fields of exclusivity.

This mapping exercise becomes increasingly difficult if the licensor is dependent on an in-licensing arrangement for the IP it plans to out-licence pursuant to the partnering transaction. The out-licence would be subject to the terms and conditions of the in-licensing arrangement, and thus will require the licensor in its partnering transaction to focus on details such as which party must control patent prosecution and enforcement or own improvements to the licensed IP, or which commercial terms must get passed through.

It is critical that the licensor ensure multiple partnerships do not conflict with one another, but it is equally important that, in conducting this mapping exercise, the licensor considers the assets or fields for which it will retain exclusive control, such as its platform technology, indications of interest or biological targets.

In contrast to the licensor, the primary objectives of the licensee are typically analogous to those of a buyer in an M&A transaction, namely, to secure the broadest rights to, and highest degree of control over, the licensed products. At the same time, much like the licensor, the licensee must account for its long-term strategy for its own pipeline development and whether it may seek to further monetise the licensed products.

Accordingly, in addition to securing the requisite rights for the licensed products, the licensee must consider how much flexibility it will need for its own future plans and its ability to enter into downstream transactions.

One key area in which the objectives of the licensor and the licensee collide in a partnering transaction is whether either party will be bound by a non-compete restriction. Similar to how a seller in a sale transaction may be bound by a non-compete in favour of the buyer, the licensee will typically seek to impose a non-compete on the licensor to ensure there is a period of time in which the licensee can carry forward the development and commercialisation of the licensed products without competing with other products controlled by the licensor, particularly given that the licensee will make a significant financial investment to enable its activities. Careful consideration must be given to an appropriately constructed non-compete restriction on the licensor, which must be narrowly tailored in scope and ancillary to the partnership arrangement. Perhaps counterintuitively, this type of provision can have procompetitive effects insofar as it is designed to align incentives between the parties to maximise the commercial potential of the licensed products.

However, caution should be exercised when constructing non-compete restrictions, particularly given today's regulatory environment in which US antitrust authorities are considering applying a heightened degree of scrutiny over the permissibility of non-compete

restrictions. Importantly, non-compete restrictions that violate antitrust laws are not only unenforceable, but they can give rise to significant liability as well.

Therefore, parties should not only carefully address the metes and bounds of a non-compete restriction to ensure it complies with antitrust law but consider whether a non-compete restriction is even necessary, and the relevant commercial concern could be addressed through other approaches.

Other provisions in the agreement may work in tandem with, or obviate the need for, certain non-compete restrictions. For example, depending on the context, in addition to or in lieu of a non-compete restriction, the licensee could consider seeking preferential rights, such as a right of first negotiation or option, with respect to competing assets controlled by the licensor for a specified term or until the licensor reaches a certain development milestone.

In addition, in certain contexts, the licensor may seek to impose a non-compete restriction on the licensee as a means of further incentivising the development and commercialisation of the licensed products. Assuming this would be commercially acceptable, the parties would need to be equally mindful of the antitrust limitations of non-compete restrictions and consider whether an alternative approach could address the licensor's concerns, including whether relatively robust diligence obligations could be imposed on the licensee that provide comfort to the licensor that the development and commercialisation of the licensed products will be prioritised.

These are just a select set of examples of the many considerations that may be considered when negotiating partnering transactions. Successful transaction execution and mitigating the risk of future disputes requires a focus on addressing the myriad transaction-specific issues that typically arise in negotiations while ensuring that the terms of the arrangement are consistent with a party's long term strategic plans.

Maintaining this dual perspective will facilitate successful collaboration between the parties, which will not only help the parties achieve their commercial objectives, but importantly, will benefit patients with unmet needs. ■