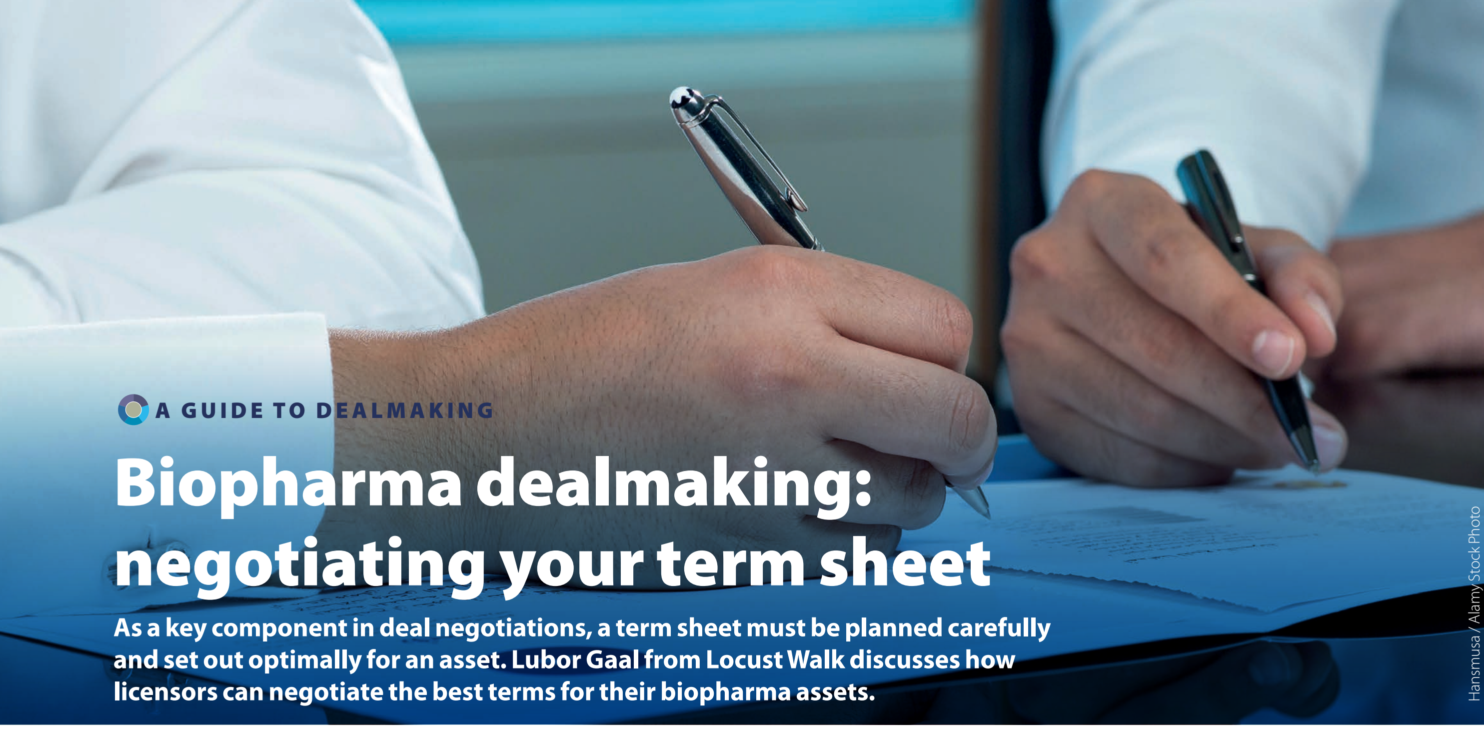

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A GUIDE TO DEALMAKING

Biopharma dealmaking: negotiating your term sheet

As a key component in deal negotiations, a term sheet must be planned carefully and set out optimally for an asset. Lubor Gaal from Locust Walk discusses how licensors can negotiate the best terms for their biopharma assets.

Lubor Gaal

One of the most important elements in a successful transaction process is the handling of the term sheet, a nonbinding agreement outlining the key conditions and financial terms for a partnership or transaction that provides the basis for the eventual contract. While there are no hard rules on how to manage a term sheet, there are good and bad practices. In this article, Lubor Gaal from Locust Walk, a global life science transaction firm, discusses some important issues in successful term sheet negotiation.

Who goes first?

The optimal timing to discuss term sheets in a transaction process can depend on many factors, including the goals of the partnering discussion. For simplification in this article, it will focus on term sheet discussions from the perspective of licensors aiming for a near-term transaction of a single asset, assuming due diligence has been conducted by potential licensees.

Deciding who goes first when drafting the term sheet can be tricky, but it should not be like a game of poker, with one company 'blinking first.' This can be avoided by building a good relationship with your business development counterpart in the potential partner company, as well as the scientific, clinical and/or commercial champions. If both parties have a similar vision for the asset, proposing terms should not be as challenging.

Inexperienced biotech companies looking to partner their assets often want potential pharma company partners to 'go first,' assuming the pharma company will offer higher terms than they dare to ask for. However, it is an important advantage for the licensor to go first, because it sets the stage for the rest of the negotiations. First, by issuing the same term sheet to all interested parties, the comparison of the different offers from potential licensees is easier. Second, the licensor can specify all the topics that are crucial to them, as well as define how detailed the term sheet needs to be before moving to contract negotiations. And third, the licensor then defines the timeline for the next step, staying in control of the process.

Components of a term sheet

It is commonly assumed that the most important parts of the term sheet are the financial aspects. However, other terms that define what rights the licensee receives or acquires with the financial offer and what other obligations the licensee enters into

Table 1 | Standard terms in a term sheet

Term	Considerations and actions if relevant
Parties	Licensor and licensee or an affiliate of licensee; check the right legal entity. The contracting party can be different from the paying party; consider tax implications as well as performance obligations if a subsidiary is licensing the product(s)
Summary	A short summary of the nature of the partnership and the reason for the agreement
Type	Define the type of agreement, for example, a license for a single compound or a strategic research collaboration for a platform technology
Licensed product(s)	Describe which compound, molecule and/or targets are being licensed; this will need to be adapted for platform technologies or broad research collaborations
Field	Define the scope of the rights, from all uses to one therapeutic area or one indication; treatment or prevention of disease; human and/or non-human use
Territory	State whether the licensing rights are global, regional or country-specific
Preclinical and clinical development	Specify who is responsible for conducting and funding all subsequent preclinical and clinical development
Governance/joint steering committee	Specify how to ensure and govern the progress of the program. A joint steering committee is common, and its scope of responsibility and decision making is often an important topic during contract negotiations
Regulatory	Specify who will lead and file regulatory submissions with health authorities in the relevant territories
Commercialization	Specify who will lead and fund all commercialization activities in relevant territories
Financial terms	See Table 2
Other	A definitive agreement will include other terms and provisions such as confidentiality, representations and warranties, indemnification, term and termination, intellectual property (joint or separate) and press releases

are equally important. As financial terms differ greatly depending on the nature of the asset, indication and development stage, this article will focus on other important standard aspects of term sheets (Table 1), as unclear definitions can undermine the drafting of the contract and create unnecessary tension during contract negotiations.

Issues that are important when selecting the right partner and that should be considered when drafting the term sheet include:

Who will govern and manage the collaboration? Governance and management of the collaboration is a key underrated topic. Regular meetings are recommended, especially in the early stages of the collaboration and when internal and external teams work closely together to advance the asset. Often a joint steering committee (JSC) will govern the collaboration and the development of the asset. Decision-making authority and escalation procedures can lead to long discussions, especially if one party has reluctantly agreed to a JSC. If it is important to progress quickly to contract negotiations, leave it for later. But if participation in the development of the asset is a critical point for the licensor, it can be a key differentiating factor.

Manufacturing costs. Manufacturing is often an overlooked topic in a term sheet, but it can be crucial, particularly for more complex molecules such as biologics. If big investments are needed, make sure that the licensee is aware and agrees to this early in the process.

Diligent development by the licensee. One of the biggest concerns for licensors is the loss of control over their licensed asset. Trust is important, but some companies prefer control, for example, through timed milestones, specifying how long each step should take. While this sounds great in theory, it is very difficult to implement in reality, and a licensee should not be penalized for taking longer if there are unforeseen problems. Other options exist to help ensure that the new partner diligently develops the asset; for example, a JSC can play a crucial role.

Exclusivity. When a potential licensee asks for exclusivity during term sheet negotiations, the pros and cons for committing to one party so early in the process need to be considered. An exclusivity fee could be considered, but this is rare for licensing negotiations. To set the right terms, the commitment from the potential licensee should be determined, as well as why they need exclusivity and what they promise to do or give in return.

Does the licensee have an internal program with the same mechanism of action? Frequently, a licensee has its own program pursuing the same mechanism of action. What happens to their internal program should be a key topic to be agreed by both parties early in the process.

Are there any special requirements? While this is not a single topic in a term sheet, it is very important to specify any special requirements that could break the deal if omitted, such as commercial rights or control over research and development activities.

Have you planned for divorce? When planning for a lifelong partnership, parties don't often consider divorce. What happens if the program does not advance as planned? And what happens after a break-up? Key questions include who owns what data or intellectual property, what will be transferred, how long will it take, and will the licensee assist with know-how (such as manufacturing) and for how long. Finally, will there be any costs or financial obligations involved?

Financial considerations

For many, term sheet discussions are mostly about agreeing on financial terms, such as upfront, milestone and royalty payments (Table 2). The trigger event for milestone payments must be clearly defined. For example, although it is standard to set a milestone for positive clinical results, 'positive' can be hard to define and agree in contract negotiations. An alternative is to use an event such as the start of the next study; instead of paying after a positive phase 1 study, for instance, select the FPFV (first patient, first visit) or another mutually agreed event.

Table 2 | Financial terms in a typical term sheet

Term	Explanation
Upfront payment	A single, nonrefundable, payment from the licensee to the licensor, due at the execution of the agreement
Option payment	The amount paid to lock up the asset until the exercise condition is triggered
Exercise payment	The amount paid to formally license the asset after triggering the option; similar to the upfront payment
Development milestones for first indication	One-time fees paid by the licensee to the licensor upon achievement of milestones such as acceptance of an investigational new drug (IND) application by the US Food and Drug Administration
Regulatory milestones for first indication	One-time fees paid by the licensee to the licensor upon achievement of milestones such as regulatory filing or approval in the US
Clinical and regulatory milestones for additional indications	One-time fees paid by the licensee to the licensor upon the achievement of milestones for additional indications
Commercial milestones	One-time fees paid by the licensee to the licensor when total net sales for a product exceed a specified threshold in a single calendar year, or cumulatively (less common); a rule of thumb is 10% of the threshold value
Royalties	Fees paid by the licensee to the licensor determined by the net sales for the product annually; rates depend on factors such as development stage, degree of innovation, competition and estimated peak commercial sales. Tiered royalties are common in standard agreements, the definition of the sales bands are crucial
Research funding	Can be specified in different ways, usually by the number of full-time employees
Royalty reduction	Specification of conditions under which royalties are reduced, for example, when generics launch, after valid patent claim expirations and payments made for third-party intellectual property

Milestones are specified only in terms of the event, not by time or date. Development of an asset can take unforeseen twists and turns, and this should not have detrimental financial consequences as long as the licensee is working diligently to progress the asset. Also, if development of the lead asset needs to be terminated, it should be agreed that development is switched to a follow-up asset, and the licensee will not subsequently pay any of the milestones for the follow-up asset that have been already paid for the original asset. However, if the lead asset is being developed for one application or indication and a second asset is being developed for different applications or indications, separate milestones should be expected.

Defining net sales is crucial for future royalty payments. While most companies wish to use their standard language, many companies try to achieve special deductions. Historically, it was possible to limit the gross to net (GTN) deductions to a fixed maximum rate, but it can be difficult to determine a number that both parties are satisfied with in today's or more importantly future reimbursement environment. GTN percentages have recently increased, and in some indications dramatically, although much less for innovative assets.

Conclusion

The process to reach an agreed term sheet can be a decisive factor in the partner selection process. If it is tough to agree on a term sheet, it could indicate that discussions could be tougher during contract negotiations. Nevertheless, some partnerships can involve term sheet negotiations that take months, with the deal negotiated and signed in weeks. Overall, the key to successful term sheet negotiations is to create a win–win situation in which both parties achieve their goals, and in the process find the right partner for their asset.

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