Professional Perspective

# Drafting Life Science Collaborations & Licenses in a Downturn

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Following unprecedented market growth in recent years, particularly in 2021, the biotechnology sector has suffered a sharp downturn in 2022. In the first half of 2022, the SPDR S&P Biotech ETF, a closely watched biotechnology index, fell over 40%. While the index has made a mild recovery, the industry has not fully rebounded, and the potential for market volatility remains a constant reality.

While the biggest effect of this downturn has been on public financings for private biotech companies, deal dynamics for collaboration and licensing transactions have also been meaningfully impacted, providing insight into key considerations for the negotiation of collaboration and licensing agreements in an unsteady environment. These considerations are likely to have a lasting impact on the future of collaboration and licensing negotiations.

This article will discuss deal process and transaction structures, economics, research and development (R&D) programs, and insolvency matters—with an aim to providing attorneys and business development professionals with the tools necessary for understanding these key considerations and identifying creative solutions to close deals.

## Deal Process & Transaction Structures

In a typical discovery-stage life sciences collaboration, a biotechnology company and pharmaceutical company collaborate on the research and development of a product or technology to determine whether to enter into a longer-term relationship. Following completion of such research and development activities, if such activities have been promising, the biotech exclusively licenses its rights in the product or technology to the pharmaceutical company that will then advance the product that arises out of the early research and development to commercialization.

The pharmaceutical company will typically pay economics in the form of upfront, milestone, and royalty payments to the biotechnology company as consideration for such license. Prior to the existing downturn, biotech companies were wielding significant leverage in negotiations due to their soaring valuations and access to markets for financings on attractive terms.

However, such companies are finding themselves in a very different market today. For example, biotech companies may receive fewer submissions in a competitive bid process with potential partners, and the total compensation offered is likely less than would have been received a year ago as bidding companies maintain a conservative cash stance. Biotechs may also need to start with counterparty term sheets or agreements, rather than insisting upon their own forms.

Deal timelines are also being extended, as internal review processes are more conservative, and boards of directors of pharma companies apply heightened scrutiny to deal approval processes. In this environment, flexibility will be key for closing deals. Companies should be prepared to think outside of the box and adopt creative solutions for transaction structures that mitigate risk, particularly when an initial deal structure fails to obtain board approval.

For example, life sciences companies may need to flip between a merger or acquisition (M&A) structure, on the one hand, and a license and collaboration structure, on the other. M&A structures, which often involve a large payment at closing, may be preferable where a buyout of stockholders is attractive, in contrast to licensing and collaboration structures which typically involve deferred economics—such as milestone and royalty payments.

However, licensing and collaboration deals typically offer future upside potential on economics. For example, a biotech company may negotiate for profit-sharing as part of a co-commercialization arrangement. In some circumstances, hybrid deal structures are being adopted, where a pharmaceutical company retains the ability to select an asset purchase or a licensing structure at a future date in order to preserve flexibility in an uncertain market.

In a downturn, life science companies need to be prepared to be flexible on deal structure to satisfy the needs of the company, while also taking into account the risk tolerance of the company's strategic decision-makers.

 

## Economics

With financing options limited, biotech companies may feel additional pressure to bring in revenue. Financial terms can consequently become a hotly debated topic in collaboration and licensing agreements. When cash is tight, it is not uncommon to see biotechs pushing for larger upfront payments, which are typically paid within days of signing of an agreement.

Licensees, however, may not be willing to pay large upfront payments, especially for early-stage R&D deals where program success is uncertain and even if successful, only significantly downstream. As a result, parties may need to think about more creative solutions, such as accepting a lower upfront payment and shifting payments to the future by tying to accomplishment of specific R&D goals.

To receive their desired economics, biotech companies may also need to consider not just licensing their rights in products, but also in platform technology. "Bundled" deals with gene editing and gene sequencing, artificial intelligence, and other technologies are becoming more popular. These bundled rights may include the right of a pharma company to use the platform technology in a broader field outside of the products themselves.

Another recent trend is an increasing number of requests for sublicensing revenue provisions in licensing and collaboration deals. These provisions entitle a licensor to a percentage of sublicensing revenue—e.g., upfronts and maintenance fees—received by a licensee in exchange for granting a sublicense to a third party. Previously, these provisions were more common in deals involving academic licensors where universities would seek to quickly monetize inventions, and less typical in deals involving two commercial entities, where pharmaceutical licensees would be responsible for de-risking programs in exchange for potential economic upside from sublicensing.

If biotech companies insist on sublicensing revenue terms, licensees can consider appropriate ways to scope these provisions. This could include, for example, decreasing the percentage of sublicensing revenue owed to the biotech company as a product advances through clinical trials and is thereby de-risked, or limiting the categories of sublicensing revenue to which such percentage would be applied.

## R&D Programs

In economic downturns, companies often tighten their purse strings with R&D funding. And when budgets are tight, collaborators may be unwilling or unable to conduct R&D activities or provide other assistance—such as consulting advice or regulatory support—to their partners. This can create points of tension in a collaboration, including in the below examples.

***Supplemental Data Requests***

A pharmaceutical company may request that its biotech counterpart deliver additional or supplemental data under a program. The biotech partner, however, may be unwilling to do so due to cost or resource constraints. Given such risks, it is critical for parties to clearly identify what data is expected to be delivered, and who pays the cost for such data, from the outset.

While it would be difficult to argue that the biotech company is not obligated to supply missing data that the agreement requires to be delivered, obligations surrounding additional data within the possession or control of the biotech company that was not originally contemplated are less clear. The same is true for new data generated through the conduct of additional studies beyond the original scope of the R&D plan.

Parties should expressly provide for data rights when negotiating a collaboration. Parties can also help minimize the risk of future disputes by listing the specific contents of a data package in a schedule to a collaboration and licensing agreement, or requiring a governance committee to determine early on the contents of a data package. And any supplemental data requests need clear metes and bounds.

Parties should also consider how to manage future data disputes that could not be contemplated when negotiating—and who has final say over such disputes.

***Control Over R&D Activities***

If a pharmaceutical company is concerned that a biotech partner may not be able to complete R&D activities under a collaborative program—e.g., due to dwindling resources—the pharmaceutical company should consider negotiating a right to assume control over certain aspects of the R&D program in lieu of a termination scenario. For example, the pharmaceutical company could request a right to step in and take over a clinical trial or could request accelerated delivery of a data package or completion of a technology transfer so that the pharmaceutical company is enabled to complete the R&D activities.

Parties will need to carefully define the specific triggers that would enable a pharmaceutical company to step-in and assume R&D activities under a collaboration, and how liability may need to shift following such step-in as a biotech company will no longer be controlling such activities.

It may also be challenging for a pharma company to convince a biotech company to fully transfer its platform technology to enable the pharma company to conduct pre-clinical discovery activities, and the pharma company may not necessarily have the expertise to fully exploit such platform technology absent assistance and training. Partners will need to think through such issues.

***De Facto Program Termination***

Alternatively, in a market where R&D budgets are slashed, a company could find that its counterpart has effectively shelved a collaborative program without formally terminating the program due to a lack of resources and having to make a choice between multiple ongoing programs—which may be well within the bounds of the negotiated efforts standard. Nonetheless, such company may still be subject to exclusivity and non-compete clauses without receiving the benefits of program advancement, such as delivery of milestone payments.

If a party anticipates that a de facto program termination may become an issue, it should consider negotiating for a right to formally terminate a program if R&D activities have not achieved certain time-based milestones, or if R&D activities have not occurred over a certain period of time.

These types of provisions can be difficult to negotiate, however, as it is sometimes unclear as to when a program is permanently shelved. For example, researchers may pause or resume programs in light of breakthroughs in scientific research or shifting business priorities. Parties should consider minimum spend thresholds and flexibility to extend these timelines if a demonstration of activity, or a demonstration that a program has only been temporarily paused, can be made to make these types of restrictions more palatable.

***Diligence Obligations***

One of the most frequent contractual disputes to arise in the licensing space centers upon whether a company is diligently advancing a program in accordance with the negotiated efforts standard—typically defined as "commercially reasonable efforts." Commercially reasonable efforts standards are highly negotiated, but most frequently allow various factors to be taken into account in the advancement of a program. Claims over whether commercially reasonable efforts have been exercised can take up significant time and resources for a company.

We are seeing companies seek to reduce this risk by requesting that diligence obligations be removed altogether at the R&D stage where a licensor has an obligation to conduct certain R&D activities prior to control shifting to the licensee. That is, the licensor must simply perform the R&D activities listed in the R&D plan, without the qualification of an efforts standard. This is particularly the case in target discovery deals.

A performing party can push back on the removal of diligence obligations, as such requests are generally not in line with market. Regardless of whether there is an efforts standard applied to R&D activities by contract, a performing party will need to take into account various factors impacting such performance—availability of resources, scientific and technical impediments, etc. If counterparties insist on removing R&D diligence obligations, parties will need to ensure that R&D plans clearly set forth all activities to be performed, timelines for performance of such activities, and objectives for such program, and that the contract limits such party's obligations to those set forth in the plan.

Where diligence standards are in fact included, parties need to give careful attention to the "commercially reasonable efforts" definition. For example, holding your counterparty to an objective standard—which looks at the efforts of a similarly

 

situated company—may offer more protection than a subjective standard—which looks at only the efforts typically used by that specific company for similar products.

Parties should pay close attention to any relevant factors incorporated into such definitions that may be impacted by tightening budgets—e.g., references to timelines and budgets, or actual or projected development, regulatory approval, manufacturing, and commercialization costs—and "catch-all" provisions that allow the party to whom the commercially reasonable efforts standard is applied to consider any "relevant factors."

## Insolvency Risks

Not surprisingly, we are also seeing increased concerns around biotech solvency. Pre-contracting financial diligence on counterparties is typically a key step to address such concerns, but increasingly we are seeing insolvency concerns as a material factor in contracting.

For example, we are seeing much more frequently a request for a security interest in the licensed intellectual property. Licensees not only want to take a license to intellectual property, but also request a security interest in such intellectual property to hedge against licensor bankruptcy risk.

These requests can present significant risks for biotech companies, as encumbrances on intellectual property are likely to negatively impact a biotech company's valuation and its ability to raise future financing. A security interest in intellectual property will also create a need for secured lender consent and subordination of the security interest in connection with future licensing transactions.

Biotech companies faced with such requests can push back by pointing to 365(n) provisions as adequately addressing the risk. Section 365(n) of the Bankruptcy Code gives licensees the right to elect to retain its rights under licensed IP where the debtor or trustee seeks to reject a license in a bankruptcy proceeding.

However, if a counterparty insists on a security interest, parties can consider ways to limit the scope of such interest. This could include, for example, limiting any security interest to a financial account such as a royalty stream—instead of legal and record title to intellectual property itself given the value of IP to a company. Parties can also consider a covenant against encumbering the applicable intellectual property—e.g., through debt transactions—without licensee's consent.

## Conclusion

While market conditions change frequently, it is anticipated that the effects of the existing downturn will continue at least into 2023, and practitioners should be prepared for risk-averse contracting strategies, like those identified above, to persist. Anticipating these strategies, with tools for counter-balancing such strategies at the ready, will be critical to negotiating the best deal terms possible for clients and driving transactions to conclusion through board approval.

Separately, deal teams will need to protect against existing market conditions driving the entire deal structure. Life sciences collaborations are—ideally—multi-decade endeavors, so ensuring that deal teams keep the bigger picture in mind throughout contracting can help to mitigate overly unfavorable terms that will create hurdles to collaboration down the road.