

Distribution agreement call options may provide life sciences acquirers with an asset preview

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As life sciences companies start to lean on M&A to replenish R&D pipelines and add revenues in anticipation of product patent cliffs, there's increasing competition for late-stage or market-ready assets. But even a promising asset after clinical trial success or FDA approval may still not be de-risked enough to invite an acquisition. There also may not be enough data available to assess the probability of production scale-up, market success, competition, and reimbursement rates.

If there is only contractual privity with the target company, and not its shareholders, there's a risk that the shareholders refuse to transfer their shares or approve the sale of assets in accordance with the call option terms.

Entering a distribution agreement with an embedded call option — in which a company agrees to market and sell the target's products, with an additional option of later acquiring the target — can be a powerful tool, allowing potential buyers to preview late-stage assets, commercialization efforts, market adoption, and other relevant data in order to help assess the potential value of the asset, as well as test the market before a full acquisition.

However, call options are not a simple contract term and must be carefully structured with a forward-looking approach. Diligence efforts must be conducted both on the front end and on an ongoing basis, just as pricing models must be structured with future valuation factors in mind to ensure that any potential acquisition transaction as a result of the exercise of such a call option can proceed as intended.

Defining the scope of intellectual property rights now may eliminate disputes later

A typical call option defines the subject matter of the option (i.e., assets, stock, etc.) and includes, among other terms, a defined exercise price or valuation methodology, a specified exercise period, and the conditions under which the option may be triggered. Any call option must account for the scope of the assets subject to potential acquisition, but a target's intellectual property portfolio could look completely different once the option is exercised.

Technologies can suddenly have new applications, derivative products can be created from existing intellectual property, competition could alter the value and market, or the target may obtain rights in additional territories.

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These circumstances can increase the risk of subsequent disputes if future intellectual property is not clearly allocated or contemplated in the instrument(s) containing the call option. Therefore, due diligence is essential to understand the full scope of target's intellectual property portfolio.

The option holder should also preserve ongoing audit rights, so that it has a full understanding of any portfolio changes before the option is exercised. Under the call option terms, the parties should ultimately have a firm understanding of whether improvements, derivative products, or new territories and indications are included in the option or if they are to be expressly excluded.

The parties may also wish to specify certain rights with respect to intellectual property while the option remains unexercised. This might include requiring the option holder's consent before abandoning an available intellectual property protection or making other material changes to its intellectual property portfolio.

Ensure contractual privity or prepare for potential roadblocks

Call options are not a simple contract term. The option holder must take steps to ensure that the call option is enforceable if exercised. If there is only contractual privity with the target company, and not its shareholders, there's a risk that the shareholders refuse to transfer their shares or approve the sale of assets in accordance with the call option terms.

Therefore, before including a call option in a distribution agreement, robust due diligence and careful understanding of the target company's capitalization structure and governance are required.

Additional legal assurances may be necessary alongside the call option, such as requiring the shareholders to execute a joinder agreement to the agreement containing the call option or ensuring that drag-along provisions in shareholder agreements will be triggered when the call is exercised. The parties must also focus on potential future stock and equity incentive issuances to ensure new additions into the capitalization structure are bound by the call option.

In some cases, structuring the call to be an asset acquisition can eliminate some of these potential roadblocks, assuming shareholder approval is not required for such a transaction. However, a sale of "substantially all assets" may nonetheless require shareholder involvement under state law or governing documents, and therefore available deal structures should be carefully analyzed on the front end. Asset sales are also inherently a structure typically disfavored by sellers (and especially shareholders).

Prepare ahead for valuation mismatches to keep incentives aligned

Pricing an option also comes with challenges. The valuation of a company or asset on the day the option is entered can vary greatly from the day it is exercised. Everything from a successful regulatory approval to a shift in the competitive market can result in a major valuation adjustment. The target company may prefer to grant a right of negotiation or right of first refusal in place of a priced call option to ensure a fair value for its shareholders.

There are strong incentives to ensure the call option valuation remains within a fair market range. Too high, and the acquisition becomes infeasible or impracticable for the option holder, while simultaneously blocking the target from other

potential acquirers. Too low, and the target's board may be unable to justify the transaction to its shareholders.

To bridge the gap, parties often seek an equitable valuation formula with a revenue multiplier or milestones. There may also be up-front payments to the potential target upon its issuance of the option to offset the target's opportunity cost of limiting other strategic alternatives.

Avoid gun-jumping and plan for premerger review

The parties must also consider any competition and antitrust issues that may arise with respect to the relationship. Firstly, the parties must consider the possibility of a premerger notification filing resulting from the transaction. Though unlikely, it is possible that, depending on how the call option is structured, an antitrust filing may be required upon execution of the call option.

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Generally, a call option in and of itself is not reportable; however, depending on the other features — like arrangements or agreements that provide "ownership" benefits — a premerger notification may be required at signing. Therefore, a detailed analysis should be undertaken with antitrust counsel, and parties' execution plan should also build in time to make such a filing if and when the call option is exercised.

Additionally, the parties need to proceed with caution during the distribution relationship to avoid any "gun jumping" issues, which refers to premerger coordination among transacting parties. Inherently, a distribution relationship will require some level of commercial coordination among the parties. The parties must structure around this and provide for robust information exchange protocols, clearly set out distribution terms that are on an arm's length basis, and leave operational control squarely with the potential target company.

Conclusion

Call options can be a valuable tool for life sciences acquirers looking to preview assets before committing to a full acquisition, allowing them to gain critical insights into commercialization viability and market performance of promising products. However, call options are not a simple contract term and require significant due diligence and planning, so that they are enforceable and lead to a successful acquisition if they are triggered.

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