

Option Deals For Biotech: Ensuring They Are Enforceable

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In recent years, big pharmaceutical companies have looked to outsource some of their more innovative and risky research and development activities as they focus efforts on their core strengths of later-stage drug development, regulatory approvals and product commercialization. Early-stage biotech companies have always needed a lot of money to finance high-risk discovery, development and regulatory approvals. While many biotech founders and investors believe their scientific efforts will generate substantial value, big pharma is often unwilling to pay significant sums to acquire products before significant derisking is undertaken. To bridge this gap, big pharma and early-stage biotech companies have turned to option deals to accomplish their respective goals.

An option deal is a transaction in which a big pharma buyer provides funding for the biotech's research efforts in exchange for the right (the "option") to acquire the assets comprising the scientific project at a prenegotiated price. The option agreement covers the rights and obligations of the partners during a R&D phase managed by the biotech company (as well as the definitive terms of the potential future buy out). It invariably contains an obligation for the big pharma company to fund all, or a substantial portion, of the R&D phase dependent on achievement of interim development milestones. At the end of the R&D phase, if the big pharma company exercises the option to acquire the biotech company, payment of the prenegotiated acquisition price is triggered. Usually, the payment of the acquisition price is structured in a manner similar to other acquisitions of prerevenue life sciences companies, including payments at the closing of the acquisition and post-closing upon achievement of regulatory or commercialization milestones.

If the option is an acquisition, as opposed to a license of intellectual property, the legal structures of option transactions are similar to conventional acquisitions — either a purchase from the target company of its assets, a purchase from the target company stockholders of their outstanding shares, or a merger of the target company with a subsidiary formed by the buyer for the purpose of making the acquisition. As with buyers in typical mergers and acquisitions transactions, one significant goal of the big pharma buyer in option transactions is deal certainty — that is, no interloper will be able to cut in on the relationship prior to exercise of the option and completion of the acquisition, and the big pharma buyer will obtain the biotech company's assets at the prenegotiated price.



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A key difference between option transactions and conventional M&A transactions, however, is that the anticipated time between entering into the option agreement and closing the acquisition is months, if not years, later. During this R&D phase of the relationship, the value of the biotech company's assets is increasing with each successful achievement of a milestone. In addition, various constituencies of the target company may be in flux over time, as equity is issued to employees, consultants and service providers, additional capital may be raised from investors and members of management and the board of directors may change. The impact of these factors on ensuring deal certainty needs to be addressed.

Choosing the Right Structure

There are various pros and cons to the various option transaction structures, as there are with more conventional acquisition transactions. Most importantly, in option deals, consideration should be given to the fact that, as a very early stage venture, the biotech company often has, or needs to obtain, investors and employees/consultants who will receive equity. For example, during a lengthy R&D phase, the biotech company often wants to incentivize new personnel through the grant of compensatory stock options. It may also need flexibility to bring in additional investors or raise additional funds from existing investors to achieve the R&D milestones, which will require it to issue new shares of stock.

If the transaction is structured as a purchase of outstanding shares of stock, then the buyer will want all present and future stockholders to sign the stock purchase agreement so it can obtain 100 percent of the stock of the company. It will also want a future investor in the target company to be bound by the prenegotiated terms of the acquisition at the time it invests. Using this structure, a buyer can be confident that, upon exercise of the option, it will acquire the target company.

If there are many stockholders, including relatively unsophisticated individuals with small numbers of shares, it may not be practical to use the stock purchase structure. If the merger or asset acquisition structure is used, different concerns are raised relating to the enforceability of the M&A agreement. In the typical M&A transaction, the expectation is that the closing will occur within a foreseeably short period of time upon satisfaction of defined closing conditions, such as third-party consents and regulatory approvals. But an option deal is not anticipated to close for many months, and sometimes years, later when the R&D milestones are met.

Several questions need to be answered when considering the merger or acquisition structure. Does the anticipated lengthy passage of time during the R&D phase affect the enforceability of the merger or acquisition agreement? What if there is a substantial change in ownership during the period between stockholder approval and closing? If the company needs to amend its charter to authorize new shares for a financing, which will necessarily change the allocation of proceeds from the date of initial stockholder approval, is the merger or acquisition agreement still enforceable?

Enforceability of a Merger or Acquisition Agreement

Delaware law does not expressly address the enforceability of a merger or acquisition agreement where there is a substantial passage of time, or changes in conditions such as these, between stockholder approval and anticipated closing. As is common with M&A transactions, the buyer in an option deal should insist on a customary no-shop provision in the agreement restricting the target company's board and management from entertaining potential competing offers. If stockholder approval is properly solicited and obtained for the agreement, stockholders cannot challenge the transaction on the basis that it was "locked-up." Therefore, at a minimum, it is important for a big pharma company to

follow Omnicare and ensure that when the merger or acquisition agreement is executed, the target company stockholder approval is not in hand — that is, there needs to be a “fiduciary out” until stockholder approval is obtained. As an added precaution, however, a big pharma company should require target company stockholders to enter into support agreements that, following stockholder approval of the transaction, preclude them from approving any other offer to acquire the company. As discussed below, those agreements should also require stockholders to ratify the agreement at a future date if requested by the buyer in case circumstances change during the R&D phase that warrant ratification.

Following stockholder approval of the merger or acquisition agreement, if the target company needs to amend its charter (for example, to raise additional funds to achieve the R&D milestones), then there is a potential conflict in two Delaware statutory provisions.[1] Pursuant to Section 242(b) of the Delaware General Corporation Law, a charter can be amended without the consent of holders of common stock in a manner that could be adverse to them, for example by authorizing more preferred stock with a significant preference. Section 251(d) of the DGCL, however, requires stockholder approval of any amendment of a merger or acquisition agreement made after adoption by the stockholders that alters or changes the agreement in a manner that adversely affects the holders of any class or series of stock. Does the amendment of the target charter constitute an amendment of the merger agreement if it adversely affects the holders of an existing class or series of capital stock? Delaware law does not expressly indicate which statutory provision has precedent, and if the charter is amended in this manner, it may give rise to stockholder attempts to prevent the consummation of the transaction. Therefore, until the Delaware courts or state legislature address this conflict, it is important for big pharma companies to ensure that the charter of the target company cannot be changed during the R&D phase of the relationship without also obtaining proper stockholder ratification of the merger or acquisition agreement by the target company stockholders. In this endeavor, the buyer should consider requiring a high level of stockholder approval for the charter amendment and ratification of the M&A agreement to minimize the risk of post-closing exercise of dissenters rights and claims relating to the transaction.

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[1] This article does not address the fiduciary duties of the target biotech company board of directors during the R&D phase.