

June 2025

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Industry Update

Biotech Spin-Off Transactions

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As we previously discussed ([here](#) and [here](#)), the biotech mergers and acquisitions market currently faces significant headwinds. These challenges include frozen capital markets, regulatory uncertainty at the Food and Drug Administration (FDA) and Department of Health and Human Services (HHS), and tariffs.

During this challenging time, there are several strategies that boards and management teams of biotech companies can consider to be well positioned to maximize value when opportunity arises — one of which is planning for creative deal structures. Here we will discuss spin-off transactions for biotechs.

There are various business reasons for biotechs to consider a “spin-off” or “partial spin-off” transaction, which involves the distribution by the company (the parent) to its shareholders of all or a portion of the stock of a subsidiary (a spinco) to which the parent has contributed a particular product or platform and related assets. After the spin-off transaction, the spinco carries on as a separate company independent of the parent, subject to any shares in the spinco retained by the parent in a partial spin-off and any ongoing contractual arrangements between the parent and spinco. An added benefit is that a spin-off can often be accomplished in a manner that is tax-free to both the parent and its shareholders.

Spin-off transactions, however, are complicated and require significant advance planning and careful implementation. Below, in part one we discuss common business reasons for biotech spin-off transactions, and in part two we discuss some key legal and business matters to consider in contemplation of a possible spin-off transaction.

1. Business Reasons for Biotech Spin-Offs

Capital Raise and IPO

Sometimes investors, boards and management believe that certain products and assets may command higher valuations if owned and managed separately, rather than as part of the same business. In the current economic environment, many investors are narrowing their focus and are interested in funding a “pure play” high growth potential asset without having to also fund slower growth assets. In such cases, a spin-off transaction can be used to attract new capital from investors that value the high potential spun-off products and assets to fund continued development or commercialization. Such a spin-off can also be combined with a subsequent initial public offering (IPO) of the pure-play spinco.

Spin + M&A

For some biotechs, there may be opportunity to monetize certain pipeline products or assets while keeping the remaining pipeline, core platform and management team intact. This can allow buyers to acquire desired assets while leaving the seller to continue developing its remaining pipeline. Biotechs can be proactive in assessing interest in their pipeline and spinning-off certain products or assets into a spinco that can enable a simpler investment thesis, out-license and/or disposition. Biotechs with drugs that have achieved key FDA milestones can sell these drugs to buyers following a spin-off, while enabling shareholders and management to continue to realize the upside of other pipeline assets.

Hub-and-Spoke Model

Biotechs with larger diverse pipelines may consider organizing numerous spinco's in a hub-and-spoke model, where administrative, research and development, and other support services are centralized in a hub company serving various spoke spinco's housing specific products. With this structure, spoke spinco's and their assets can opportunistically be sold off to pharma companies or receive direct investments, with the remaining structure staying intact to progress the balance of the pipeline. The hub-and-spoke model can also create efficiencies and facilitate drug discovery by, among other things, recycling capital and aligning management incentives based on the individual pace of products.

Spin-Off Merger With Pharma

Spin-off mergers can be considered where pharma buyers wish to acquire a biotech's clinical or near-clinical stage products but are not interested in its early-stage products, or where the biotech's management is interested in continuing to develop those early-stage products. The pharma buyer would leave behind the assets it does not wish to own (or pay for) and the biotech shareholders would continue to realize value from those assets. In this situation, the parent separates its early-stage assets into a spinco, then distributes the shares of the spinco to its shareholders and, immediately after the spin-off is completed, the parent (which retained the clinical stage assets) merges with a pharma buyer. Spin-off mergers have been implemented in the public company M&A context where a public biotech agreed to spin out its pipeline assets to its shareholders before being acquired by a pharma buyer in an all-cash merger.

2. Spin-Off Considerations and Planning Matters

Spin-off transactions are complicated, time-consuming and expensive, and can trigger problems for the parent if not planned and implemented carefully. Below, we discuss briefly some key legal and business matters to consider in contemplation of a possible spin-off transaction. Before undertaking a spin-off, the parent should consider the potential value of the spinoff shares for tax and other reasons. These issues become more complex in a spin-off combined with an IPO or other capital markets transaction, or in a spin-off that is part of a larger merger or business combination.

Tax Matters

A biotech spin-off transaction presents various tax opportunities and challenges, depending on the specific facts and business objectives. Where the biotech is a corporation for U.S. federal income tax purposes, it may be possible to effect a tax-free spin-off. In a tax-free spin-off, generally the parent will not recognize corporate-level gain and its shareholders will not recognize dividend income.

In order to qualify as a tax-free spin-off, numerous statutory and nonstatutory requirements must be satisfied. This includes the requirement that both the parent and spinco are engaged in an "active trade or business" that has been conducted for at least five years prior to the distribution, and that the parent must "control" spinco (i.e., own at least 80% of the total number of shares of spinco entitled to vote and 80% of

the shares of each class of nonvoting spinco stock) immediately before the distribution and distribute an amount of spinco stock constituting control in the spin-off.

Ensuring that a spin-off is tax free can be time consuming, in part because it is necessary to develop the facts supporting the satisfaction of the tax requirements and to manage legal uncertainty, to the extent possible, often by obtaining a private letter ruling from the Internal Revenue Service. Given timing, it may be possible to raise additional equity capital at spinco in the interim while maintaining parent control (i.e., a new investor could invest for no more than 20% of the total number of shares of spinco entitled to vote and 20% of the shares of each class of nonvoting spinco stock) in anticipation of a future tax-free spin-off.

In this regard, biotechs will need to balance the potential tax benefits of a tax-free spin with the projected additional costs incurred to ensure tax-free treatment. Alternatively, it may be possible to distribute future growth with respect to a spinco in a so-called corporate freeze transaction while incurring less upfront tax as compared to a full taxable spin-off.

The most efficient structure depends heavily on the specific facts with respect to the various businesses involved and the composition of a biotech's current investors. As no single tax approach will work for every biotech, early examination of the facts and development of a tax plan is crucial.

Intellectual Property and Licensing

Spin-offs can present complexity in terms of allocating assets and liabilities between the parent and spinco and effecting their actual separation, which may require third party and regulatory consents. Addressing shared intellectual property (IP), including which party will keep the IP and what cross-licenses may be put in place, is of particular importance for biotechs where different drug programs can be dependent upon the same or similar underlying IP. The parties often need to enter into transition services agreements, contract manufacturing or facilities sharing arrangements, IP licenses and data sharing arrangements. Some of these complexities can be less burdensome in an early-stage pipeline spin-out, where the assets may be easier to define and separate.

Business and Management Separation

Planning for a spin-off involves identifying assets and liabilities to be separated, allocation of employees, identifying and addressing shared assets and contracts, consents, waivers, notices and possibly transition services agreements. If the businesses to be separated are tightly integrated or are expected to have significant business relationships following the spin-off, it could take more time and effort to allocate assets and liabilities, identify personnel that will be transferred, separate employee benefits plans, obtain consents relating to contracts and other rights, and document ongoing arrangements for shared services (e.g., legal, finance, human resources and information technology) and continuing supply, intellectual property sharing and other commercial or operating agreements.

Legal and Contractual Considerations

Spin-offs implicate a number of possible legal and regulatory matters that must be examined in the planning stages. For example, depending on the value of the spin-off assets in relation to the value of the parent's retained assets, the spin-off may be deemed to constitute "substantially all" of the assets of the parent under applicable state corporation law, which ordinarily would require parent shareholder approval. Additionally, the distribution would have to comply with state corporation laws dealing with the payment of lawful dividends by the parent.

Spin-off transactions may trigger applicable antidilution protections under outstanding warrants or other securities of the parent company, rights of first refusal provisions or other contractual obligations of the parent or among shareholders. These issues, among others, should be thoroughly considered before undertaking a spin-off transaction.

Public Company Considerations

Public company biotechs considering a spin-off transaction will also have to consider the implications of SEC rules on the transaction. Whether or not the spinco is or will be an SEC reporting company will be an important consideration. A spin-off of a public company must be registered with the SEC, which is an extensive process that can take six months or more, requiring IPO-level disclosure and separate audited financial statements for the spinco business.

Paul Hastings Life Sciences, M&A and Tax attorneys are here to help companies and investors assess possible spin-off transactions. Please feel free to contact us.



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