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Biotech Collaborations Can Ease Uncertainty Amid FDA Shift

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Biotechs have faced several challenging years with slumping valuations and a competitive funding environment. However, the latest slew of retirements and layoffs at the U.S. Food and Drug Administration could present their greatest challenge yet.

While the new FDA Commissioner Martin Makary has promised speedier approvals and shorter drug development timelines, concerns persist that the agency's reduced headcount will impede approval pathways. Companies are already reporting longer wait times for clinical trial design review and scheduling meetings with FDA personnel.[1]

These delays, by necessity, extend the timeline for drug approval, requiring biotech companies to fund operations for a longer period pending commercial product launch.

With biotech companies already pushing their cash runways to the limit, volatility in the public market and private funding at a premium, companies are turning to collaborative deal structures as an alternative source of financing and to reduce their burn rate.

Licensing and Collaborations as Alternative Sources of Financing

Out-licensing of noncore assets can provide an alternative financing option to biotech companies encountering fundraising challenges in the current market.

Typically, these deals include an up-front cash payment with additional amounts payable upon achieving certain developmental and/or commercial milestones, as well as a royalty on net sales of the resulting products. This cash can then be used to fund development of the company's core technology.

For early-stage assets, or when the innovator biotech has specific expertise beneficial to the ongoing development of a technology, a development collaboration may be more appropriate.

Unlike an out-license, where the innovator company generally cedes control of the development process to the licensee, biotechs entering into a collaboration generally partner on the development of a product or products.

Typically, the collaboration agreement allocates responsibility for certain areas to each party and includes a requirement that the parties form a committee composed of representatives from each to oversee the entirety of the development process and to assist in decision-making and dispute resolution.

The ideal collaboration partner is one who has specific strengths — like research and development, clinical study design, manufacturing, sales force or market access — that the innovator company does not and that are needed to efficiently advance the project.

By partnering, biotechs can tap into these additional resources with no cash outlay, thereby reducing the financial burden and speeding the path to product approval, often getting a cash infusion.

In addition, biotechs without an established sales force or physician coverage for their product can leverage their collaboration partner's network and reduce cash burn related to hiring sales staff at the commercialization stage.

In return, the collaboration partner obtains rights to market and sell the resulting product for certain therapeutic indications and/or in certain markets and geography, with the innovator retaining the balance of these rights.

Partnerships and collaborations can often lead to the acquisition of the innovator by the collaboration partner as the partner better understands the product and potential upside.

High-demand drug markets are already seeing these types of deals in action. For example, the obesity drug space is anticipated to generate more than $100 billion in revenue by 2030.[2]

In a recent move, Zealand Pharma AS entered into a collaboration with pharmaceutical giant Hoffmann-La Roche AG to commercialize an amylin analog that can be used in obesity treatment.

This $5.3 billion deal — composed of up-front and milestone payments — allowed Zealand to avoid having to sell itself, thereby preserving future upside from commercialization of the product to its shareholders.

In addition, the transaction allows Zealand to benefit from Roche's global infrastructure and commercialization expertise. The transaction was on the tails of several other biotech licensing and collaborations in the obesity drug space in the first half of 2025.

Hart-Scott-Rodino Filings Could Cause Deal Slowdowns

One potentially countervailing factor is the impact of Hart-Scott-Rodino Act filing obligations.

The HSR Act mandates that parties exceeding certain size thresholds undertaking acquisitions over a certain size notify the government — specifically, the U.S. Department of Justice and Federal Trade Commission — in advance of closing their transaction to allow the government time to review the proposed acquisition transactions for potential anticompetitive effects.

HSR can also apply to certain patent licensing arrangements, such as those involving exclusive licenses transferring all commercially significant rights with respect to certain medical and botanical products,

pharmaceutical preparations, in-vitro diagnostic substances and biological products. Commercially significant rights include grants of exclusive geographic territories or fields of use.

For these types of license transactions this year, HSR filing obligations apply if one of the parties is engaged in U.S. commerce, the parties have annual sales or assets of at least $252.9 million and $25.3 million, respectively, and the transaction is valued at more than $126.4 million.

For purposes of calculating the transaction value, the parties are required to estimate the total value of all payments over the life of the arrangement, not just the up-front payment. If the value of the transaction exceeds $505.8 million, it is reportable regardless of the size of the parties.

If the thresholds are met, both parties must file premerger notification forms and observe a 30-day waiting period before completing the transaction. The 30-day period may be extended if the government issues a request for additional information.

While many expected the current administration to sideline HSR reforms, new rules went into effect on Feb. 10, which are estimated to extend contractual filing timelines from less than 10 days to at least 30, due to more burdensome reporting requirements.

In addition, new leadership at the FTC and DOJ have indicated their intent to focus on deals in the pharmaceutical and health care industries as part of the administration's broader efforts to lower health care costs and promote competition.

For example, the FTC has challenged the acquisition of a manufacturer of coatings for medical devices and continued its litigation against pharmacy benefits managers, while the DOJ has continued its challenge to the combination of two large home health providers.

Also, on June 11, the FTC, DOJ, U.S. Department of Health and Human Services and U.S. Department of Commerce announced three joint listening sessions on lowering Americans' drug prices through competition, which will include panels regarding generic and biosimilar availability, prescription drug formularies and benefits and regulatory barriers.

The sessions are intended to inform the FTC and DOJ's joint report on reducing anticompetitive behavior of pharmaceutical manufacturers, as contemplated by an April executive order.

Therefore, licensing arrangements should be assessed for HSR applicability and filing obligations, and strategies for managing competition risk should be built into any deal timeline on the front end.

Aside from the size-of-person test, two principal questions often must be examined to determine whether an HSR filing is required and a waiting period observed: whether the proposed license will transfer commercially significant rights and whether the valuation of the license exceeds the applicable size-of-transaction test.

The HSR regulations define commercially significant rights as "the exclusive rights to a patent that allow only the recipient of the exclusive patent rights to use the patent in a particular therapeutic area (or specific indication

within a therapeutic area)."

The license need not transfer all the rights to make, use and sell. The governing principle is whether the licensee will receive the rights that generate profits. For example, a patent holder retaining limited manufacturing rights would still be viewed as a transfer of commercially significant rights under the HSR rules.

Although the FTC has provided guidance around this language, HSR counsel will need to understand exactly which rights will be transferred and which will remain with the patent holder, and the standard is somewhat ambiguous.

The scope of these rights frequently change during the course of the license negotiations, affecting the analysis under the HSR regulations.

Patent license valuation is also a significant question to HSR reportability and can often be difficult to determine. The acquisition price for an exclusive license is equal to the gross amount of future royalties due under the license agreement during the life of the license and milestone payments payable if certain clinical developmental targets or FDA approval are achieved.

When future royalties are too speculative to estimate reasonably, the acquisition price is considered "undetermined," and the value of the license is the current fair market value of a fully paid-up license.

According to FTC staff guidance, the fair market value of U.S. patents should be determined using a method that is consistent with the method used for determining the value of the overall patent portfolio. The value should include any goodwill, know-how or other intangible assets allocated to those U.S. patents.

The board of the acquiring person or its designee is responsible for determining the value in good faith. The agency does not have a preferred method of valuation and does not give advice on what method is appropriate.

Beyond the HSR reporting obligation questions, any product portfolio or development pipeline overlaps between the licensee and the patentholder should be identified in order to determine the extent of the information required for the HSR filing and whether the enforcement agencies might have any concerns.

Under the new HSR rules, the time required to prepare the submission is significant, particularly because greater client interaction is necessary and typically the parties already have many other tasks to accomplish in furtherance of the licensing arrangement.

Additionally, to draft the necessary responses and locate the information required under the current rules involves more judgment calls that can only be made after counsel has a good understanding of the markets or potential markets and pipeline.

Further, this understanding is essential to decisions regarding timing and whether any antitrust risks affect the licensing agreement itself, including, for example, the appropriateness of exclusivity, pricing provisions, duration and restrictions development.

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Conclusion

As biotech companies navigate FDA uncertainties and economic pressures, licensing and collaboration transactions can provide the necessary funding and pathways to advance innovative products. However, the current market and political climate will nonetheless affect deal terms and transaction considerations.

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[1] https://www.law360.com/articles/2315013/fda-cuts-prompt-biotech-players-to-rethink-deal-strategies.

[2] https://www.law360.com/healthcare-authority/articles/1839686/a-changing-regulatory-landscape-for-weight-loss-drugs.

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