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Embattled Biotechs Facing Uncertainty at the FDA Look to Collaborative Deal Structures

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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 FDA could present their greatest challenge yet.

While the new FDA commissioner 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. 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 markets, 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 upfront 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(ies).

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 comprised 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/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. In a recent move, Zealand Pharma entered into a collaboration with pharmaceutical giant Roche to commercialize an amylin analog that can be used in obesity treatment. This $5.3 billion dollar deal (comprised of upfront 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 2025.

Hart-Scott-Rodino Filings Could Cause Deal Slowdowns

One potentially countervailing factor is the impact of Hart-Scott-Rodino (HSR) filing obligations.

The HSR Act mandates that parties exceeding certain size thresholds undertaking acquisitions over a certain size notify the government (U.S. Department of Justice (DOJ) and Federal Trade Commission (FTC)) 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 in 2025, 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 upfront 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 February 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, in an April executive order, FTC, DOJ, and Health and Human Services were ordered to

conduct joint public listening sessions and issue a report and recommendations to reduce anticompetitive behavior of pharmaceutical manufacturers.

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.

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 impact deal terms and transaction considerations.

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