Proskauer

BridgeBio Transaction Reflects Healthy Market for FDA Priority Review Vouchers

Proskauer in Life Sciences Blog on **May 17, 2022**

BridgeBio's recently announced sale of an FDA Priority Review Voucher for $110 million reflects a robust secondary market for these regulatory fast passes. Prices for Priority Review Voucher ("PRVs") reflect the high stakes involved in the timing of the FDA review of a new drug application ("NDA") or biologic license application ("BLA"). While the purchase of a voucher can help a drug's sponsor shorten the time to market, it can also put immediate cash in the hands of the voucher seller seeking to tide itself over, particularly during a period of flagging investor interest in the biopharma sector.

PRVs arose as a Congressionally authorized incentive for drug companies to develop treatments for tropical and rare pediatric diseases, and for medical countermeasures against chemical, biological, radiological, and nuclear threats. When the FDA approves a sponsor's drug in one of these three areas, it awards the sponsor a PRV. The PRV, which is transferrable, can later be redeemed by the PRV holder to claim a priority review of an NDA or BLA by the FDA, which targets a six-month turnaround instead of the standard ten months. The benefit of such expedited review, as described in the U.S. Government Accountability Office's report to Congress when the PRV program was up for extension in January 2020, is "… the potential for additional revenue that comes from marketing a drug approximately 4 months sooner—or the proceeds that may come from selling the PRV to another drug sponsor …" (Available at GAO-20-251, DRUG DEVELOPMENT: FDA's Priority Review Voucher Programs.)

Since the first PRV was awarded by the FDA in 2009, fewer than three dozen PRVs have been issued in total, most recently to COVID-19 vaccine applicants. Over the course of the program, the prices paid for PRVs have fluctuated widely. The high water mark appears to have been United Therapeutics' sale of its PRV to AbbVie in 2015 for $350 million. The least amount reported to have been paid for a PRV was BioMarin's sale to Sanofi and Regeneron for $67 million in 2014. *Id.*, at GAO. BridgeBio Pharma's sale this May for $110 million, transacted nearer to the lower than the higher end of the range.

Given the many factors that influence sellers' and buyers' assessments of value, PRV prices are likely to continue to fluctuate despite their limited supply. From the purchaser's perspective, the perception of value is largely based on the product the PRV will be used for. If that product has a large addressable market and there is an opportunity to beat competitors' therapies to the market, a head start could have significant value. From the seller's perspective, a sale may represent an opportunity to monetize a non-core asset, raising the capital needed to advance its own drug development programs. In a challenging capital markets environment, a PRV sale for cash upfront may be an attractive option for sustaining cash runway.

View Original

Related Professionals

- **Robert A. Cantone**