CHALLENGES IN VALUATION - THE IN-LICENSING PERSPECTIVE

WHAT IS A VALUATION?

Let's first make sure we are all on the same page when we say "valuation". In its simplest form, a valuation is a calculation of the risk-adjusted net present value of a drug candidate. It takes all revenues and expenses into consideration, then adjusts everything for risk and the time value of money. Transaction expenses, such as upfront payments, milestone payments, and royalty payments, are also included.

The net result of these calculation is "The Pie", which is a simple pie chart of the candidate's risk-adjusted net present value, but also showing how the project value is divided between a licensee and a licensor.

Once a base case version is established, different scenarios can be prepared, examining different assumptions regarding patient share capture, pricing, development costs and timelines, and many other factors. These models can be relatively simple at first and increase in complexity and sophistication as negotiations with prospective partners evolve. Monte Carlo, real options, game theory, and other advanced techniques can also be employed as these models evolve.

THE IN-LICENSING PERSPECTIVE

Valuation from an in-licensing perspective necessitates the introduction of issues and challenges which are simply not present (or minimally so) in a valuation exercise from the out-licensing perspective. In this article, we highlight some of these challenges.

1. Stand Alone Value

At its core, a valuation analysis must support the underlying hypothesis that the drug candidate / opportunity has value and merit which exceed the licensee's predetermined expectations around risk, reward, franchise fit, and other factors. In our experience, ebullient claims about market size and revenue potential fall apart quickly under mild pressure. Thus, it is probably quite rare to find in-licensing opportunities which have legitimate shots at achieving licensor revenue forecasts. In-licensing teams with solid guidelines will quickly eliminate these opportunities, usually without detailed valuation analysis.

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2. Underestimation of Development and Regulatory Risk(s)

It is exceedingly rare for companies experienced in the art of in-licensing to underestimate development and/or regulatory risks. But it does happen. Approximately 10-20% of FDA submissions result in a Complete Response Letter (CRL) per annum, effectively signaling the non-approval of a submission.[1]

The reasons for these CRLs may vary, but insufficient clinical data and manufacturing issues are common reasons for non-approvals. If a company does not know that the clinical development plan will be insufficient, what does this say about the diligence and valuation process? Is it naïve? Rushed? What about after the transaction?

3. Franchise Synergy

A *franchise* in this context can be thought of as a brand with a presence across multiple therapeutic areas / audiences (such as *Humira*) OR a brand with an incredibly deep presence within a large therapeutic area (i.e., *Keytruda*). The successful launch of a brand, with the intention of building out a franchise, requires incredible amounts of resources across the entire value chain. Once these investments are made, it is critical to ensure that additional opportunities flow into the sourcing and assessment process which can leverage these investments.

It is often challenging for licensors to fully grasp the underlying value associated with a franchise. Clearly, franchise synergy will drive sourcing, but what about assessment and valuation? How will Opportunity A be a better fit with the existing (or emerging) franchise when compared with Opportunity B? These are rather complex questions, as numerous assumptions must be made about various infrastructure issues, such as incremental marketing spend (and the resulting marginal ROI). Importantly, franchise fit considerations must be made in the context of other opportunities, which will be discussed later.

Franchises are frequently understood in the context of real options, a subject which will not be detailed here. Suffice to say that a real option is a situation where an option holder has the option, but not the obligation, to execute on a particular strategy or tactic. Options can take many forms, such as the option to invest in an additional clinical program, or the option to abandon a development program, or the option to acquire (or license) a candidate (or an entire company) at some point in the future. Like options to buy and sell equity, real options have a value, and an implied expiration date. Thus, franchises lend themselves quite well to real options analyses.

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There are many options inherent in franchises, such as the option to invest in an additional Phase III program to seek another approval in another indication. However, real options analyses sometimes suffer from two disadvantages. First, they can be construed to overvalue an opportunity, since the real options value is in addition to any risk-adjusted discounted cash flow models. Second, the calculations involved may seem complex, and unfamiliar to those not practiced in the art. Comparisons to other opportunities with fewer or no real options can also be challenging, both from a calculation and an explanation or presentation perspective.

4. Decisions and More Decisions

Many (but not all) companies who are actively in-licensing are also performing some level of candidate product development. These candidates may come from internal discovery efforts, from prior in-licensing successes, or both. Thus, a decision between in-licensing and investing in the newly licensed program and an investment in existing internal programs must be made. Complicating the decision process even further, there is also the option of an out-right acquisition, either of the company currently under evaluation, companies who own candidates previously licensed, or yet another acquisition opportunity unrelated to prior licensing activities.

This is a tremendous challenge from a valuation perspective because the underlying valuation model structures can be quite different for these situations, making direct comparisons, and therefore, decision making, quite difficult. Even relatively mundane topics, such as tax implications, will vary depending on the type of transaction being contemplated.

5. Competition

While these decisions are being contemplated, our competitors are not standing still. They too are struggling with the same decisions. More importantly, their successes and failures can have direct implications for our own strategies. For instance, a competitor who announces very successful Phase III results may result in our inability to achieve First-To-Market status. Could this make a difference in the valuation of our internal candidate? Or in the valuation of the prospective in-licensing opportunities? Of course, it will. But the degree of this difference will need careful scenario modeling, with an element of real options and game theory to enable deeper analysis.

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6. Timing…and Courage

Adding to the complexity of decision making is the reality that things can change overnight. New competitor data, challenges in other parts of the business, internal disagreements on strategic direction and tactics…all these dynamics can make a good decision made on a Monday seem like a poor decision by Thursday. At some point, somebody will have to take a decision.

CLOSING

Compared to valuation from an out-licensing perspective, valuation from an in-licensing perspective is far more complicated. There are simply many more strategic, infrastructure, and parallel investment opportunities that must be considered. Even if an in-licensing opportunity has tremendous value as a stand-alone opportunity, these other issues may play key roles in the overall valuation of a single opportunity. Thus, it is critical to have in-licensing valuation methodologies and processes which enable input and insights from a wide range of personnel within an organisation.

[1] Silverman, B, US FDA's Use Of CRLs Hit A High Note In 2022: One-Third Of Novel Agent Decisions Were Not Approvals. Pink Sheet Perspectives, January 9, 2023.] *https://pink.pharmaintelligence.informa.com/PS147548/US-FDAs-Use-Of-CRLs-Hit-A-High-Note-In-2022-One-Third-Of-Novel-Agent-Decisions-Were-Not-Approvals*

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