Opportunity Assessment Through the In-Licensor's Lens

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For an emerging biotech, a traditional commercial opportunity assessment is an essential part of the partnering process for a development-stage asset. This assessment provides an in-depth market understanding to support investment toward commercialization, and as such provides the ideal information for conversations with potential partners. However, there are additional, critical considerations that can ensure a well-rounded conversation.

This white paper is the third in our "Growing Up Biotech" series. The two previous papers ("Taking the Long View: Translating Science and Technology into Commercial Opportunity" and "To Partner or Not to Partner: Determining Your Commercialization Plan") discussed the technical and transactional assessments required to identify the right type of partnership for a biotech's asset or platform and overall business needs.

Here, we move beyond these components to discuss the need for an outside-in perspective—one that ensures a biotech is putting itself in the mindset of other companies and individually considering the differences between potential partners. It is easy to overlook this dimension; however, open conversations and an understanding of each party's needs can foster confidence and trust. If neither party goes beyond the base opportunity assessment, discrepancies in perception and valuation can emerge, delaying and sometimes derailing the partnership process.

Of course, viewing the opportunity through the in-licensor's lens is easier said than done. It is important to consider a framework for this evaluation.

In this white paper we lay out a simple framework for the out-licensor, which we assume here is a small or mid-sized emerging biotech company, to consider when viewing the partnering opportunity through the in-licensor's lens (Figure 1) – though importantly these insights apply equally for larger pharma companies and other partnering scenarios. For this framework, we initially review characteristics related to the potential partner's business development culture and typical preferences. We then walk through several common reasons a partner would be interested in a specific asset or platform. Finally, in this paper we will highlight how to leverage these perspectives from the in-licensor's lens to realize the payoffs before, during, and after initial pitch conversations.

Growing Up Biotech

Beginning at inception, emerging biotech companies experience a sequence of hurdles and uncertainties while pursuing the launch of their first product. From the initial conversation with investors and in-licensors to the subsequent steps post-launch, ClearView Healthcare Partners' white paper series "Growing Up Biotech" identifies and addresses strategic clinical and commercial questions companies are likely to encounter while exploring common barriers and critical success factors that are often overlooked.

Understanding Your Partner's Business Development Culture

It is essential to remember that an in-licensor's view of an opportunity encompasses more than the asset's or platform's direct valuation. As an out-licensor, displaying thoughtfulness regarding these other factors and engaging in the personal element inherent to partnership discussions can build comfort, confidence, and respect across the table. That can then translate into more productive meetings and a more efficient transaction process whereby both parties are aligned around the same tangible and intangible determinants of value.

In particular, understanding an in-licensor's preferences and deal history can temper expectations and better position an out-licensor for success. With this in mind, reviewing the potential partner's past agreements and collaborations should focus on several key questions:

- Does the potential partner typically engage in co-development or co-commercialization deals? Does this differ by therapeutic area or phase of development?

Viewing a Partnering Opportunity Through the In-Licensor's Lens	
UNDERSTANDING A PARTNER'S BUSINESS DEVELOPMENT PREFERENCES	**CONSIDERING A PARTNER'S RATIONALE FOR THE DEAL**
• Co-development vs commercialization • Geographic rights predilections • Desired phase of development • Typical deal terms	• Expanding or evergreening an existing portfolio • Developing a new franchise, potentially in a new therapeutic area

Source: ClearView Healthcare Partners

- What is the in-licensor's record in seeking geographic rights for an early-stage asset or platform? Does the company typically ask for global rights including the U.S. or prefer regional deals?

- What degree of clinical validation, or phase of development, does the in-licensor seek out?

- What are the usual deal terms? How do deal terms differ based on the above?

While the above questions do not encompass an exhaustive set of key probes, they represent a foundational starting point to reveal the type of quid the in-licensor often seeks for the quo. Moreover, these questions can touch upon the potential partner company's business development culture and negotiating habits. Knowing the answer to these and other questions can help refine the list of high priority companies to engage with, not to mention inform pitch presentations and posture going into negotiations. Finally, taking this extra step promotes confidence in the licensor and builds rapport between the two parties.

Considering Your Partner's Rationale for the Deal

A solid understanding of the in-licensor's business needs can differentiate the out-licensor in a partner's mind. Being able to step away from personal goals and think from the in-licensor's perspective can generate interest and trust in downstream negotiations. Notably, and as a critical caveat, we perceive this to be information that is important, but perhaps kept off the page. Particularly in the early stages of talks, the out-licensor does not want to go too far out on a limb, assumptions about why the in-licensor might value the asset may be best introduced after both parties have been through multiple conversations.

A potential partner will have many motivators and considerations for why they are seeking to license an asset. These usually fall into two broad categories. Most potential partners are either:

1. Expanding or evergreening an existing portfolio, or

2. Developing a new franchise, potentially in a new therapeutic area

A brief review of publically available sources such as the partner's website, press releases, or quarterly investor reports will reveal the in-licensor's position regarding each consideration. Here we review these considerations to understand what they are and how to identify them.

Expand or Evergreen an Existing Portfolio

A licensor may have multiple reasons to build out an existing portfolio. Several common reasons are provided below, though critically these are neither exhaustive nor mutually exclusive, and in fact they may contribute collectively to engender interest in licensing a new platform or asset.

Achieve Commercial Synergies in a Growing Portfolio

The in-licensor may be interested in bringing in an asset that fits within an existing therapeutic area, enabling the sales force to call on the same physician with an expanded number of related products. If the target provider is similar, the in-licensor can take advantage of synergies between an existing franchise and the potential in-licensed drug. For example, Gilead has engaged in several deals as it builds its liver franchise (See Case Study 1).

Expand the Portfolio to Provide a Continuum of Product Offerings to Stakeholders

In many cases a potential partner will already have launched products in a given disease area. However, these products may not address all patients. For example, the in-licensor may have a drug for mild and moderate patients, and is looking for a novel therapy to address the severe patient population. By acquiring or partnering for the novel asset, the partner company would be positioned to offer a "continuum of care" for that particular disease. For example Sunovion markets nebulized products, such as Brovona for COPD, and recently acquired Novartis' inhaled line of COPD agents to expand its product offerings across the continuum of care.

A Continuum of Care

CASE 1: GILEAD'S PORTFOLIO EXPANSION

California-based Gilead is expanding its liver disease franchise, established through its hepatitis C vaccine (HCV) portfolio, by building a strong presence in nonalcoholic steatohepatitis (NASH). To that end Gilead picked up NASH assets when it acquired Phenex Pharmaceuticals and Arresto Biosciences, and more recently when it licensed an ACC inhibitor from Nimbus Therapeutics.

Source: ClearView Healthcare Partners

Capitalize on Potential for Combination or Sequential Therapy

It may be, particularly in the era of targeted oncology and cancer immunotherapy, that an out-licensor's asset paired with the partner's existing drug provides combination opportunities. This is the case with Exelixis' collaboration with Genentech testing cobimetinib (MEK inhibitor) in combination with atezolizumab (anti-PD-L1 antibody) in three different cancers. Multiple other examples can be identified in oncology alone, particularly given the plethora of partnerships around the PD-(L)1 checkpoint inhibitor class of drugs.

Limit Competitive Threats

New therapies that improve upon the existing standard of care can serve as significant competitive threats to companies with established offerings in a particular disease area. In such a situation, the established player may seek out novel assets to better compete in the evolving landscape and preserve the portfolio's long-term growth potential. For example, Shire has been active in the HAE space and previously acquired Dyax to gain access to the latter company's subcutaneous prophylactic pipeline agent, which has potential to be a meaningful improvement over current infused options.

Extend the Lifecycle of an Aging Brand

An in-licensor may have an aging product whose patent is about to expire. Without additional assets in the pipeline, the in-licensor may soon face a meaningful commercial gap. As such, the company may be seeking companies with assets that can complement the existing portfolio and provide for longer-term lifecycle management and continued revenue generation. For example, Astellas recently acquired Ogeda, whose lead asset for vasomotor symptoms would build upon Astellas' strong and longstanding genitourinary portfolio, which includes Myrbetriq (mirabegron) and VESIcare (solifenacin succinate), the latter of which loses patent protection in October 2018.

Develop a New Franchise, Potentially in a New Therapeutic Area

Potential partners looking to develop a new franchise or enter a new therapeutic area must decide whether to build it internally or buy into it. Building it from the ground-up through internal clinical development capabilities takes time and comes with the usual set of associated clinical risks. A new therapeutic area may also require net new technical and clinical capabilities that are not already existent in-house. As a result, a potential partner may opt to acquire their way into the market by pursuing deals.

Quickly Build Out a New Franchise

For an in-licensor to build out a new area quickly, partnering on or acquiring products/companies is a viable means to achieve that goal. For example, Takeda has been seeking to expand into the rare disease space (See Case Study 2).

Garner Market Experience in a New Area

This can often occur prior to the launch of an independent, pre-existing internal asset. A company that decides to enter a new market may have assets in early stages of development with substantial promise. To ensure an effective launch for those assets, it may be beneficial for the company to gain commercial experience and generate physician relationships in that market. One means of achieving this objective would be to acquire or partner with an out-licensor that has a later-stage asset anticipated to launch in the near-term. This may have been part of Amgen's motivation for in-licensing U.S. rights to Servier's heart failure drug Corlanor, which provides Amgen with market presence and experience ahead of its anticipated launch of omecamtiv mecarbil.

> **Fast Track: Building a New Franchise**
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> **CASE 2:**
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> **TAKEDA'S RARE DISEASE PURSUIT**
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> Early this year, Takeda inked a deal with Ovid Therapeutics to aid their entry into rare disease. The partnership consists of a split team which couples Takeda's resources with Ovid's technical expertise for TAK-935, a candidate for rare epileptic encephalopathies. In so doing, the partnership will allow each party to realize mutual benefits.
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> Source: ClearView Healthcare Partners

Acquire Internal Expertise or Technical Platform Capabilities

With the desire to start up a new franchise or therapeutic area, several needs could be bundled with the in-licensor's product. These might include technical or regulatory expertise, manufacturing capabilities, or access to novel technology platforms. Novartis is emblematic of this approach, entering into several deals to gain access to new treatment approaches. Most notable are Novartis' forays into chimeric antigen receptor T cell

(CAR-T) therapy, originally with the University of Pennsylvania and expanded through collaborations with Intellia and Caribou to leverage their CRISPR/Cas9 genome editing technologies.

How to Leverage Perspectives from the In-Licensor's Lens

Understanding the rationale for an in-licensor's interest in a deal can be leveraged across various aspects of the partnership process. Here, we break this down into three general stages: before company communications, during the pitch process, and through to closure of the transaction (See Figure 2).

Companies seeking to out-license a product or technology are typically incredibly busy, and incorporating additional research is not an easy task. However, the modest investment in time up front can save a greater amount of time down the road, and lead to a more successful outcome. Specifically, the early research on potential partners can identify higher priority companies to target for initial communications and pitch presentations. In so doing, the out-licensor can avoid spending time preparing for and presenting to companies with a lower likelihood of interest. This is analogous to a typical job search. While it may be easy to blast an application to nearly every company, a minimal degree of research initially to identify top targets and tailor a resume and cover letter for those openings is likely to yield better results and potentially save time overall.

Once a set of potential partners is identified, it is critical to create a positive impression and generate interest in the asset or technology being discussed. Having a better understanding of the partner company's products, pipeline, and business development tendencies will enable the out-licensor to better position the pitch presentation. An important note is that this information does not need to be put into slides, but may be better suited for off-the-page comments and discussion. Additionally, demonstration of initial due diligence by the out-licensor can build confidence in the team and can suggest that a similar degree of preparation and rigor have gone into the asset or technology assessment. Not surprisingly, therefore, preparation before pitch conversations can improve the odds of accomplishing follow-up conversations.

Example Benefits of Understanding the Partner's Perspective

Source: ClearView Healthcare Partners

Finally, as conversations shift to a potential transaction, the earlier investment by the out-licensor to consider the partner's interests and goals can lead to a greater likelihood of closing the deal. Much of the reason for this relates to the rapport and respect that is built through the partnership process, which can often be underestimated by out-licensors. It could be a deal breaker if a partner company does not believe that it will be easy, enjoyable, or productive to interact with the out-licensor during or after a transaction closes. Conversely, mutual appreciation and shared values can increase transactional efficiency and result in a greater desire to close the deal.

Conclusion

Often viewed as "above and beyond," the extra step to understand the partnership from the other company's perspective should be included in all out-licensing discussion preparations. Doing so will save time, create efficiencies, increase partner rapport, and lead to a greater likelihood of closing a deal.

About ClearView Healthcare Partners

Founded in 2007, ClearView Healthcare Partners is a global strategy consulting firm serving the life science sector. The firm combines international industry knowledge and deep scientific expertise across a range of therapeutic areas with an extensive network of external stakeholders to deliver practical and actionable recommendations to our clients' most complex challenges. The firm's projects include cross-functional support at the corporate, franchise, and product levels for pharmaceutical, biotech, medical device, and diagnostics companies worldwide.

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