

Asset Identification Series

Early Stage Asset Identification

Rationale

The cost of drug development, from initial research through NME approval, now exceeds \$1.3 billion in out-of-pocket expenses¹, resulting in a substantial commitment as well as a serious financial drain on pharmaceutical companies. In order to combat these high barriers and reduce the strain on internal research and development teams, it is becoming more common to turn to outside sources². Options for outsourcing can include identifying target groups for acquisition, as well as evaluating specific technologies for licensing opportunities.

Challenges

The first challenge in establishing a licensing agreement or the foundations for an acquisition is finding an asset worth investing in. This can be challenging due to the very high volume of researchers and startups looking for funding as well as the relatively high risk involved in developing early-stage products. Several factors should be considered to optimize the selection of an asset before moving on to evaluating and structuring potential agreements. This article will provide a framework for the asset identification and selection process.

Beginning the Search

The initial step of an effective search is to clearly define the search criteria. There are many different therapeutic areas and markets within the healthcare industry, so one important question is to narrow down the therapeutic categories of interest. Most established pharmaceutical companies already have a handful of therapeutic areas in which they are invested or interested in expanding into.

An evaluation of the current portfolio provides a picture of what areas the company is active in, which areas may be expanding or in development, and which areas may be lagging behind. In evaluating each area, it is important to consider several factors, including market size, competition, and types of treatments. An acquisition or licensing agreement should only proceed when a suitable match is found for all of these factors.

Market size is determined by the treatable population and the cost of treatment. If there are any changes in diagnostic methods for a given condition, the treatable (diagnosed) population may expand. If there is an increase in preventive care, the treatable population may decline. It is important to take into account any potential changes in these markets within the next several years, even those in very early stages of research.

Pricing will be more closely determined by competition. It is important to understand what new therapies competitors may be developing in the space as well as to understand how your current products stack up to current competitors. In some cases, it is wise to consider a licensing agreement in order to prevent a competitor from licensing the same technology and gaining a competitive advantage.

Often times, pharmaceutical companies find it more efficient to specialize into specific types of treatments. For example, a company with experience dealing in specialty, injectable biologics may have an easier time supporting development of more products in this category than a company with no prior experience. For these reasons, the types of therapy in development (by licensing targets, as well as competitors) should be considered. If it is possible to align a specialized type of treatment with a therapeutic category of interest, this should be pursued.

Identifying Opportunities

Once therapeutic areas of interest are determined, data should be collected on potential opportunities within this space. Early leads can come from networking (at both academic and industry events), publicly available information (such as company websites and press releases), or published research.

Larger pharmaceutical companies tend to develop internal groups and structures for analyzing opportunities. Often, these teams are solicited directly by companies looking for out-licensing opportunities. This approach can be a good, low-effort, source of early leads, but the self-selective nature will lead to less targeted candidates.

Many companies also find it advantageous to use third-party databases or matching services. These types of services maintain information on developing technology in various therapeutic areas. One service offered by BluePrint Orphan is access to a curated database of partnership opportunities. This database consists of the most current information on cutting-edge technologies and platforms, including pipeline phases and expected timelines. For more information on our services contact us at info@blueprintorphan.com.

Finally, academic institutions can make excellent partners in the development of new technology and products. If possible, it is important to keep up on current trends in academic research within the selected therapeutic areas. This can be done through reading new publications, attending conferences, and networking with those in the academic space.

Screening and Evaluation

Often times, many leads will accrue from the sources outlined above. In order to move quickly and capitalize on the best opportunities, it is wise to implement a quick initial screen. The goal of this is to understand performance and capabilities³.

Performance should be evaluated based on the therapeutic area's sales and growth over the past several years. Recent trends should be taken into account, as well as expected changes in the area. This should give a good idea of the market size, as well as the rate of change to expect. It is also important to

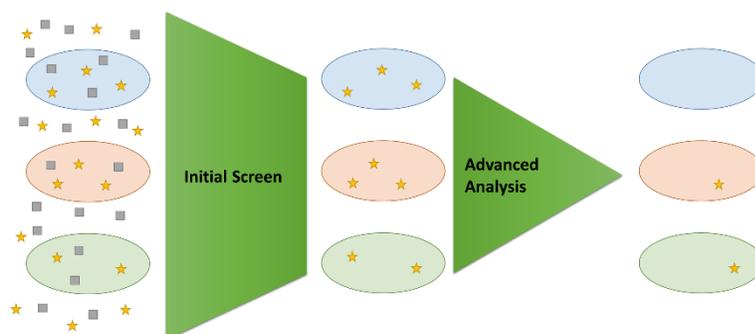
evaluate the existing competition and current pricing space. These pieces will be the framework of a more complete evaluation, discussed **in the second part of this series**.

Capabilities reflect the quality of the potential partner. This evaluation should be based on any existing strategic relationships that the potential partner has. It should also take into account existing data around market access, therapeutic pipelines, and other relevant information. It is highly recommended to come up with an internal framework for this evaluation process to ensure that each potential technology is evaluated objectively and given a score. Once each candidate has been awarded a score, the highest-scoring should be selected for more in-depth evaluation.

Be Realistic

In competitive, quickly developing spaces, it can be tempting to wait for a silver bullet to come along matching all desirable criteria. It is likely, however, that even the best opportunities will not be a perfect fit. Understanding this and being willing to evaluate imperfect opportunities is critical to a successful asset search.

The asset search should begin with identification of key therapeutic areas, followed by an initial screen to eliminate weaker candidates, and finally advanced quantitative analysis to select the ideal partners and begin the formulation of an agreement



¹ Tufts Center for the Study of Drug Development. (2014, November 18). Retrieved from http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study

² Lachman, R., & Samet, M., Ph.D. (2005, June 5). The Art and Process of Successful In-Licensing. Retrieved from <http://www.biopharminternational.com/art-and-process-successful-licensing>

³ Finding and Executing Pharma Licensing Opportunities. Retrieved from <http://www.pharmaventures.com/consult/white/paper/6>