

Structure in-licensing

Take a rational approach to assessing the relative commercial attractiveness of new opportunities

Specific in-licensing activities may be driven by certain commercial pressures, such as the need for increased speed to market versus an in-house compound or to fill a specific gap caused by failure of an in-house product, but overall licensing activity requires a more strategic approach. A simple but effective process can be used to assess the relative commercial attractiveness of a large number of specific diseases/indications across a therapeutic area. This provides the core commercial input to developing a robust licensing strategy and a strong framework against which individual licensing candidates can be evaluated.

Imagine a situation where a company has a portfolio of established brands across a small number of indications in one therapeutic area. The company has made considerable investment in these brands, generating high brand equity, excellent customer relationships and good sales. However, the real issue is a suboptimal R&D pipeline giving it limited ability to capitalise on its current strong position. It makes sense to consider in-licensing additional products to expand the portfolio. In this way, the company can capitalise on its KOL and prescriber relationships and S&M expertise to maintain or expand its position.

This is not simply about evaluating another product for the same indications in which the company is established. It is about assessing the relative commercial attractiveness of additional new diseases or indications in order to provide strategic direction to business development and licensing teams on future disease areas with high commercial opportunity. This provides a 'search and selection' focus for business development activities and a framework against which individual products can then be considered.

Clearly, developing a licensing strategy is about more than identifying the commercial opportunity; it is equally about the technical attractiveness of an area and 'company fit'. To shape an in-licensing strategy, areas where high commercial and technical attractiveness combine with good company fit must be identified. This article focuses on assessing the commercial attractiveness and company fit aspects and describes a step-by-step approach to assessing the relative commercial attractiveness of a large number of diseases/indications.

OVERVIEW

A practical, six-step approach provides rapid initial assessment to determine which of a large number of diseases/indications could be most commercially attractive and therefore worthy of more in-depth evaluation as a strategic licensing target. Here a simplified version of what would be needed in the real world is presented.

The key steps are:

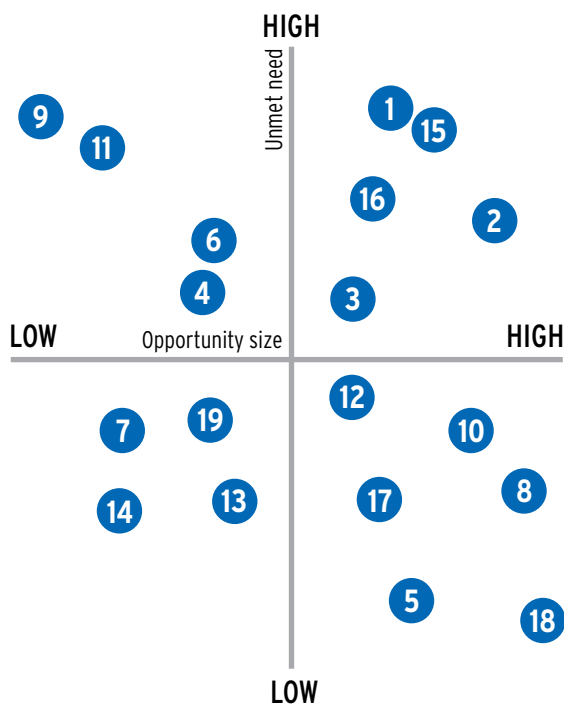
- Selection of parameters by which commercial

- attractiveness will be evaluated
- Weighting parameters in terms of importance
- Scoring each disease using a consistent approach
- Data collection on each disease/indication
- Data quality assessment
- Company fit.

1. Parameters for defining commercial attractiveness

The first step is to determine which parameters make a disease 'attractive' as a commercial opportunity. This means starting with the end in mind, to define how to differentiate between particular opportunities. The following example assumes that the objective is to evaluate a therapy area containing 30 different diseases or separate indications in order to identify the five most attractive diseases as potential targets for licensing (or other investment) activity. There are no right or wrong parameters, but in this illustration 'unmet need' and 'opportunity size' are chosen to form the axes on the differentiation grid (Figure 1).

FIGURE 1. EXAMPLE DIFFERENTIATION GRID FOR EVALUATING COMMERCIAL ATTRACTIVENESS



Each circle represents one disease/indication

Plotting all 30 diseases on to this grid identifies those which fall into the top right corner (i.e. high unmet need and high opportunity size). Depending on a company's overall strategy, diseases in other quadrants such as high unmet need but a smaller opportunity size may also be attractive. For example, GlaxoSmithKline's Rare Disease Unit might have a different definition of 'attractive' to that of a team focused on large primary care opportunities, hence the need to tailor the definition of commercial attractiveness to specific business objectives.

In order to plot drugs on to this grid, they first need to be scored for each parameter. For opportunity size, the obvious starting point is epidemiology, but this will not be sufficient; a



TABLE 1. WEIGHTING OF CRITERIA ACCORDING TO IMPORTANCE

OPPORTUNITY SIZE

Market size (epi)	Competition in 2016	Etc	Total
60%	30%	10%	100%

UNMET NEED

Treatments available now	Price potential	Etc	Total
50%	30%	20%	100%

➔ large number of patients with a large number of anticipated competitors could result in a smaller opportunity size than the epidemiology alone would suggest. Similarly, with unmet need, in addition to clinical need, factors such as price potential and the effectiveness of current treatments will also have an impact. It is important not to use too many criteria to contribute to each axis, otherwise there is a risk of them cancelling each other out, thereby reducing the differentiation between products. Experience suggests that eight criteria (four for each axis) should be the maximum, and generally six will give good differentiation.

2. Weighting system

Not all criteria are equally important; for instance, it may be decided that market size is the biggest contributor to opportunity size, in which case this criterion can be given a higher weighting accordingly (Table 1).

3. Scoring system

When comparing across 30 different diseases, it is essential to use the same criteria to assess each, and to apply these criteria consistently. The scoring key (Table 2) shows how clear definitions have been developed for

each criterion. Each disease is awarded stars (points) for each criterion, with five stars reflecting the most commercially attractive option and one star the least.

4. Data collection

Once the process and criteria have been agreed, data collection can begin. This should not be an overwhelming task but should focus on the criteria by which the disease will be scored. Using a template helps. It is important to capture the information and reference sources; this provides transparency around assumptions and serves as a baseline should new information become available. It is then possible to update the information, revise the scores and calculate a new position on the grid.

A capable researcher should be able to research each disease and summarise the data in about half a day.

5. Data quality assessment

The level and quality of supporting data for each criterion will vary, and it is important to understand which assessments are based on robust data sources and which on limited information. Table 3 (over page) shows a format for capturing this information at a glance. A simple traffic-light system is overlaid



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TABLE 2. EXAMPLE KEY FOR SCORING DISEASES/INDICATIONS FOR EACH CRITERION

	★★★★★	★★★★	★★★	★★	★
Market size	>1%	~0.1%	~0.01%	~0.001%	~0.0001%
Treatments available now	Few treatments available: significant unmet need remains	Some treatments available: high unmet need remains	Treatments available but room for improvement e.g. better efficacy	Many effective treatments available	Resolves without treatment
Competition in 2016	Nothing in development	Current status: mostly early stage products	Current status: mixture early-late stage products	Current status: mostly late stage products	Current status: pending approval
Price potential	>\$15,000 per year	n/a	~\$5,000 per year	n/a	<\$100 per year

on each score for each of the 30 diseases, with green cells denoting robust data, such as multiple sources of high-quality consistent information, and red cells reflecting limited or conflicting data whereby further research may be required.


6. Company fit

Once the research and scoring have been completed, the output can be summarised on the differentiation grid (Figure 2). If required, bubble size and bubble colour can be used to capture additional information. Here, bubble size has been used to reflect ‘fit with company relationships’; a larger bubble shows diseases which are treated by physician groups already well known to the company (with potential sales and marketing synergies), while the smaller bubbles reflect a potential new target audience. Bubble colour can also be used to provide a quick visual reference to any other parameter of interest.

COMMERCIAL ASSESSMENT

This process provides a practical and effective tool for looking across a large number of diseases to identify those of greatest commercial attractiveness.

All aspects, from process definition to data capture and the final ranking of relative commercial attractiveness, can be managed using a simple Excel model. This has the advantage of being easily updated with new information and allowing ‘live’ exploration of ‘what if’ scenarios in team workshops, such as changing the weighting given to the importance of epidemiology versus competition and seeing how this impacts a disease’s position on the differentiation grid.

What makes a project like this successful? This type of assessment has two phases. The first three steps relate to developing the process and differentiation criteria. Experience suggests that the critical success factor here is stakeholder 

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Rob Wood, STEM Marketing

TABLE 3. TRAFFIC-LIGHT SYSTEM FOR DISPLAYING THE SCORES FOR EACH DISEASE/INDICATION

Disease Number	Market size (epi)	Competition in 2016	Treatments available in 2016	Price potential	Etc	Overall score
1	5	3	2	4	1	3.1
2	4	3	2	1	2	2.6
3	4	2	2	4	1	3.2
4	3	4	5	5	5	4.5
5	3	3	3	2	2	2.8

engagement. There is never one simple right or wrong process or parameter for any project; it will be influenced by a range of factors, including corporate business objectives, organisational culture, time frames and therapy area. Workshops can provide an effective means of getting stakeholder input into this part of the process. The second stage is about data collection and interpretation, where the key success factor here is collecting the right data, not just a volume of data: focus is key. Real benefit is to be gained by having a researcher who knows more than how to access a database. He should fully understand the business question and how the data relates to this.

Finally, an external facilitator experienced with this type of process can provide constructive challenge and a fresh perspective, as well as keep the project focused on its core business objective.

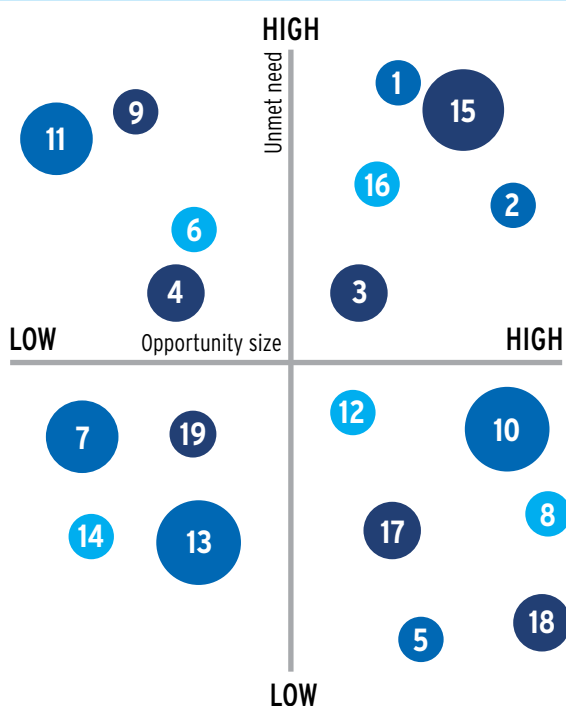
This process provides a broad approach to prioritise rapidly the relative commercial attractiveness of a large number of diseases. The five diseases offering greatest relative commercial attractiveness can then be explored in greater depth, in terms of more detailed assessment of commercial attractiveness and exploration of technical attractiveness/

feasibility. These can be combined to create a structure for identifying diseases/indications as potential targets for licensing activity (or in-house investment) and provide a framework against which individual candidates can be compared.

The Authors

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FIGURE 2. DIFFERENTIATION GRID SHOWING RESULTS OF DISEASE/INDICATION SCORING



Each circle represents one disease/indication

Executive summary

- A strategic approach should guide search and selection of potential licensing candidates
- Understand the commercial attractiveness of potential new opportunities
- Use an effective process for looking across a large number of diseases to identify those of greatest commercial attractiveness
- Careful consideration of assessment criteria, and stakeholder engagement in this process, is critical
- Work with senior researchers who understand the business questions and who can identify the commercially critical information
- The process identifies the best opportunities and provides a direction for search and selection and a framework to assess specific candidates