Is your early drug candidate ready to partner?

By Linda Pullan, Pullan Consulting

Pullan Consulting (www.PullanConsulting.com) often helps with "partnerability assessments", checking for answers to these 10 questions.

1. Is this kind of asset on many company shopping lists?

Partners look for impact and strategic fit.

- Big impact – important unmet need or a big market
- Fit with the sales force
- Fit with the gap in pipeline (both for resource use and revenue delivery)
- Fit with their focus ("We are an Ab company" or "We do cutting-edge science").

There are potential partners for virtually any indication, but some are much harder than others. Some indications (like oncology) have many, many companies seeking opportunities, but also lots of competition. Some indications (antibiotics) have very few companies seeking drug candidates because, for example, new drugs are reserved for resistance, limiting their application in larger market 1st-line applications. (We track what companies say they want in our CRM).

2. Is it an indication with many failures?

Indications that have seen many clinical stage failures (for example, sepsis) may be difficult to partner until a clinical breakthrough has established a new beachhead for success. Sometimes, biology is complicated and regulatory endpoints required are uncertain, and partners may want to see more risk reduction before partnering. (We can provide probabilities of success by stage for various indications).

3. Are the mechanism and disease really competitive? Are you late to enter?

Are you trying to enter a crowded space? Typically, sales decline rapidly from the market leader's sales numbers for each new entry (market order of entry) unless there is substantial differentiation. (We can help you see the competition in the pipeline and think

about unmet needs for effective differentiation.) Competing against generics makes it hard to price high and make more money. (We can provide sales and price information, patent expiries, and pipelines of competitors).

4. Is there good validation of the target?

Are there human genetics linking the target to the disease? Is there intervention success with a knock-out (or overexpression), tool compounds, and the preclinical candidate? (We can help you determine if your target validation data is what industry is looking for)

5. Is the data clear and compelling?

Many deals are done at preclinical and discovery stages. Generally, deals for drug candidates are done when the mechanism is established in vitro and in vivo. Most deals are done with in-vivo efficacy in an animal model. But some animal models are not well correlated with efficacy in humans; this has been a terrible problem for immune-oncology models. This may mean you have to wait for human efficacy to be sufficiently compelling to partner for an IO program with a new mechanism. (We can help you assess the competitive landscape and what data may be needed for a deal for a given indication).

6. Is there a barrier to competition?

First, your drug should not be limited by other IP; freedom to operate is, of course, essential. Then, the most desirable barrier to competition is typically a Composition of Matter (COM) patent with a good exploration of the possible structure activity relationships of other active molecules. Orphan drug designation in the US, Japan and China protects only the same molecule in the same indication. So off-label use remains a threat. Deals are sometimes done without COM IP or orphan drug designation, but the royalties are typically reduced.

7. Are there biomarkers for target effect (dose selection), patient selection?

Companies hate to do a trial while not knowing whether the dose tested was sufficient to test the mechanistic hypothesis. A clinical trial with a large effect in a reasonably large subpopulation selected by a biomarker is much more appealing than an all-comers trial with a small effect size. Thinking about possible biomarkers or biomarker strategies can be very worthwhile.

8. Is there a good path to approval and to persuade physicians and payors?

Young biotech companies sometimes do not spend enough time thinking about the regulatory endpoints and the data that will be needed to persuade physicians and payors to use and pay for your drug in the future. If you need a cardiac events trial for approval (such as for type 2 diabetes in the US), that is a huge cost. If physicians and payors are largely satisfied with a cheap generic, you will need data demonstrating an important difference to persuade them to change. For a preclinical deal, you don't need a lot of detail in your commercial thinking, but partners may not put in any effort to evaluate an opportunity unless you can tell them there is a good path to capture future sales. (We can help with market research reports or analyst reports on many indications).

9. Can you manufacture the drug?

Manufacturability is important even in early assessments for a preclinical deal. Instability can lead to immunogenicity, poor bioavailability, and lack of efficacy. And recently, many FDA Complete Response Letters not approving a drug were for manufacturing problems.

10. Can the risks be removed early?

No early drug candidate is without risks, and you don't have to remove all the risks before partnering. But a risk that can be addressed early by the partner means much less money and time spent fruitlessly. (In some indications, we can tell you what concerns we hear from partners for other opportunities).

If you would like to help assessing the partnerability of your drug candidate, or other help with partnering, please contact us: **Linda@pullanconsulting.com**. We work with clients with therapeutics and therapeutic platforms from discovery to Phase 3, typically getting half-a-dozen to a dozen signed deals a year.