

Top Tips...

With **David Scott**Course leader for **Fundamentals of Pharmaceutical and Biotech Licensing**



David Scott is a freelance certified licensing and business development consultant, with proven skills in deal-brokering, marketing, strategic planning, finance, business development and acquisitions.

With over 30 years' experience, he is author of a number of best-selling licensing guides and also runs licensing training courses for companies and organizations in the healthcare sector.

Plan what you want to achieve before you start

Whilst licensing activities don't always work out the way you intended, there can be no doubt that planning and preparation are critical to its success. As American General and President Dwight Eisenhower once said, "In preparing for battle, I have always found that plans are useless but planning is indispensable."

So, decide at the start of any licensing activity why you are doing it and what you want to get out of it. This will mean examining your corporate objectives and deciding how licensing can help you achieve them. For instance, do you have products in your portfolio that do not fit in terms of the clinicians you visit that should be out-licensed to someone better able to exploit them? Do you have a gap in the therapeutic range you offer that can be filled by in-licensing? If so, then you should profile the ideal product and use that as a basis for searching opportunities both on the market and in R&D.

Or perhaps you lack the finance or development resources to take a new opportunity through to the market, in which case you need to profile the sort of partner best able to do this for you.

If you know precisely what you are seeking and what you have to offer, not only are you more likely to achieve your objectives, but you will also make your company appear as a more attractive partner for those able to help you get there

2 Before opening discussions with a potential partner, agree your target and fall-back termsheet internally

The value of a product is a complex mixture of its inherent value (how well is it protected, how effective is it compared with existing therapies), potential demand (how badly does a partner want it, how will it impact on the rest of the business and how many companies are offering or seeking similar products) and what sort of deal you are offering (is it global, is it exclusive?).



Ultimately, if you are out-licensing, the primary objective is to maximise the return you can achieve, but at the same time you do not want to ask for too high a price and find no one is interested. So, before you start it is important to be clear what type of deal you are seeking, in terms of structure (which countries are included, will your partner manufacture, will they own the trademark?) and in terms of values. Get senior management to buy-in to these numbers, so when you do a deal, no one can say "why did you settle for 10% royalty when you might have got 12%?".

You should also be clear what the fall-back position will be. If your board insists it wants a \$1m up-front as an absolute minimum, you don't want to waste your time negotiating with a company unwilling (or unable) to pay.

With pre-agreed parameters, your negotiating position will be much clearer for potential partners to understand, and you will avoid wasting time negotiating with someone who ultimately will not deliver what you want.

3 Don't try and make short cuts when it comes to evaluation and due diligence

The evaluation and due diligence process is resource intensive for licensors and licensees alike. The licensee needs to be clear that the product on offer can deliver, particularly if it is still in R&D, and it is the job of the scientists in the licensor company to make sure the information to enable them to do this in an accurate and easily understood way. That requires time and effort from both sides, and can involve people from many different departments, including staff from R&D, clinical development, sales and marketing, production, finance, insurance and intellectual proerty.



In most cases, licensing activity by other departments is unbudgeted, and freeing up time to complete the evaluation may mean delaying other projects. However, if the licensee misunderstands, then the project will likely fail and both partners will lose out. Even worse, if the licensor provides inaccurate information and that results in the failure of the project, then the licensee may be able to sue them.

So, whilst making the resource available may cause operating problems for both partners, the consequences of failing to properly complete the process can be disastrous, so do make sure you have included sufficient resources

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Fundamentals of Pharmaceutical and Biotech Licensing https://ebdgroup.knect365.com/pharmaceutical-and-biotech-licensing/

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To find out more about our courses and how they will transform the way you work, contact our training consultants:

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