Licensing to big pharma – virtues and vices

Most, if not all, founding scientists who enter the high risk world of commercial biotechnology have a driving ambition to make a contribution to the improvement of human healthcare. Unfortunately the path to bring innovative medicines to market is long and extremely expensive. Hence sooner or later a development partner with big pockets will be needed.
Martyn Postle, Director of the consultancy Cambridge Healthcare & Biotech, discusses the pros and cons of releasing equity versus licensing to a development partner.

In the "good old days" (which, for the purposes of this article, I consider to be around a decade ago) a biotech company with a decent management team and a half-way decent prospect would probably have been able to obtain venture funding to take that project through until the end of early human clinical trials, before seeking the deep pocketed pharma partner. Indeed, many of them would have assumed that the eventual royalty income generated by their pharma partner may even have allowed them to take their next project further through development themselves. This would have enabled them to retain an even higher share of the total profits from their IP. Some even had aspirations of evolving towards becoming fully integrated niche pharmaceutical companies.

However, in the last five years the bubble of optimism around the traditional business model of the independent biotechnology company has well and truly burst. Access to venture funding for biotech companies had dried some time before the bubble also burst for financial institutions in general towards the end of last year. At the end of 2008 we saw the biotech industry in the US and the UK approach their respective governments 'cap in hand' to ask for a bail-out. It remains to be seen whether they will be successful in their entreaties, but until then the pharmaceutical industry seems to be the only source of funding for biotech companies.

More than just deep pockets

Hence pharmaceutical development partners have taken on a new financial role in the last few years. No longer are they 'mere' providers of development funding plus the occasional injection of cash via milestone payments due through licensing deals. In most cases they are the only source of equity financing for biotech and licensing deals are now much more likely to include an upfront equity injection as part of the package.

Table 1: The pros and cons of both types of deals as seen from biotech and pharma perspectives.

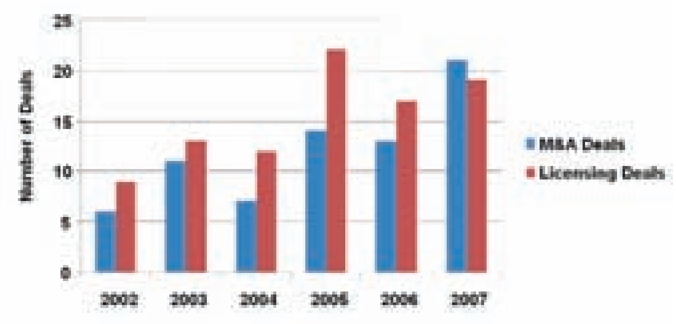
Viewpoint	Deal type	The Virtues	The Vices
Biotech	Out-license	•Independence maintained •Royalty income equates to 'real' product revenue stream •Multiple partners can be sought for the same project for different indications •Either technology or product deals can be pursued •Flexibility in deal terms possible (but we'd like most of the value upfront or in early milestones please) •We get an endorsement of our technology which can help with other deals, or financing •Licensing deals could lead to acquisitions/exits (often the first thought of VC board members of the biotech company)	•We retain most of the high risk of failure •Although you say our product is high priority for you now, you have a habit of changing your mind later and there will probably be little we can do about it then •Once our 'jewel in the crown' is out-licensed we may not be an attractive acquisition candidate any more making VC exit even more difficult
	Divestment	•We hope that pharma's impoverished pipeline will mean it will potentially pay a high price for ownership	•Early divestment will almost certainly involve selling it cheaply •Once our 'jewel in the crown' is sold we may have very little of value left making VC exit impossible
Pharma	In-license	•If it doesn't work we won't have paid much for it •Flexibility in deal terms possible (but we'd like most of the value end-weighted please). •If biotech is cash strapped they will have to take what we are prepared to give them as an up-front	•We may not have full control on development •We will have to pay eventual royalties (unless we buy the company) which could be very costly if the product becomes a blockbuster
	Acquisition	If it works it will have been cheaper to buy it than license it (or, indeed, buy your whole company) •We have complete control •All eventual profits will come to us •An acquisition may give us the chance to restructure our R&D engine into a more efficient model •Our company may benefit from an injection of your culture	•We have to take on all the risk of failure •If we acquire, we may have to acquire your problems as well as our benefits

But an equity injection will now always be welcomed by the biotech company. It does mean that options to exploit their future IP may become more restricted depending on the terms of the agreement, or at least the attractiveness of the biotech as an acquisition target by a third party will certainly be diminished.

Acquisitions overtake licensing deals

In early 2008 we sponsored a review of trends in licensing and M&A deals amongst UK biotech companies[1] and found that although the numbers of both types of deals had been increasing, for the first time in 2007 the number of acquisitions of UK biotech companies was greater than the number of licensing deals involving UK companies (see below).

Number of M&A and licensing deals involving UK biotechs



Things seem to have slowed down through 2008. Although we do not yet have the data for the UK, a recent review by EvaluatePharma's EP Vantage group indicates that total licensing deals in 2008 were down 23% over 2007 to 422 individual product deals.[2]

In any case there are virtues and vices of licensing versus acquisition and these will, of course, depend on whose eyes you are looking through. Table 1 gives our view of the pros and cons of both types of deals as seen from biotech and pharma perspectives.

Selecting an ideal partner

On the assumption that licensing deals are still the 'deal type of choice' between biotech and pharma companies, we conducted a survey of out-licensing biotechs and in-licensing pharma companies throughout 2008 to ask them what they were looking for in an 'deal' partner. The overall results of that survey are shown in Table 2.

Perhaps not surprisingly both types of company ranked "obvious commitment to the deal" as the most important consideration in a partner, with "good communications" and "direct access to decision makers" high on the list.

Looking for different criteria

Given the current climate, it is also not surprising that "willingness to pay significant up-front" ranked at number 3 for biotechs (but only at number 10 for pharma), while the rankings were reversed for "prepared to be flexible in deal structure" which was number 3 for pharma respondents and only number 11 for biotechs. Indeed, we have heard anecdotally from a number of biotech clients recently that pharma companies currently seem prepared to sign deals with very high royalty rates attached (presumably on the assumption that if the project looks promising in late stage development they will then acquire the biotech partner before the royalties ever become payable). However, the same sources tell us that negotiations on up-fronts and early milestone payments are now much more challenging.

One criterion which we believe will change is that the partner provides "an opportunity for a future M&A deal". At present this criterion is almost at the bottom for both pharma and biotech. However, we believe that as pharma and biotech realise that they will only be able to look to each other for new products and funding for those products, each licensing deal will be assessed for its ability to provide an attractive M&A opportunity.

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Table 2: What are pharma and biotech companies looking for in a licensing partner?[3]

How important are the following qualities when looking for a partner? Please assign a level of importance to each of the following qualities	Overall ranking all respondents (n=45)	Biotech ranking (n=25)	Pharma ranking (n=20)
Obvious commitment to the deal	1	1	1
Good communications during negotiations	2	2	2
You can directly access partner's key decision makers	3	4	4
Prepared to be flexible in deal structure	4	11	3
Willingness to pay significant up-front	5	3	10
Have good track record with regulatory bodies	6	10	6
Reputation in the market as a good partner	7	12	5
Established franchise in target therapy area	8	9	8
No in-house conflicting product or IP	9	13	7
Ability to deal quickly	10	8	9
Geographic coverage	11	6	13
Clinical development capabilities	12	5	17
Product development capabilities	13	7	19
Track record with new product launches	14	14	12
Empathy with your company's culture & objectives	15	18	11
Strong financial performance of partner	16	16	15
Sales force size	17	15	24
Sales force specialism	18	17	21
Shape of gap in partner's pipeline	19	20	16
Willingness to develop your IP in further indications	20	22	14
Partner has necessary research capabilities	21	23	18
Partner has access to key clinical investigators	22	19	23
Partner will have positive impact on your share price	23	21	20
Opportunity for future M&A deal	24	24	22
Partner's manufacturing capabilities	25	25	25

1 License or Buy? Current trends in the Biotech Sector and Recommended Strategic Options: The UK Perspective. CH&B sponsored study by Gigi Wong, M.Phil student at the Institute of Biotechnology, University of Cambridge 2008

2 See http://www.epvantage.com/

3 Cambridge Healthcare & Biotech licensing survey 2008