

Co-development deals – How to determine the terms

We observe an increasing willingness of biotech companies to enter co-development deals. Usually investors are in biotech for the big wins. When out-licensing a project a company gives up most of the upside potential in exchange of early and certain upfront and milestone and some relatively moderate royalty payments. An investor on one hand is interested in securing value and reducing risk by his portfolio companies entering license agreements, but on the other hand also wants a substantial upside potential for his investment, which to a large extent is lost by plain out-licensing. Co-development deals are attractive way to go, by securitising value and reducing risk, but keeping a part of the upside potential. Even if they won't commercialise the project at the end, co-development deals still allow to take projects to a later phase and then to license them for higher better terms.

As long as these deals are structured in a strictly symmetrical way, i.e. each party contributes 50% to the development, negotiation and further licensing is usually unproblematic. But as soon as one party enters the scene only when the project has already undergone some development, deal terms are subject of discussions. The joining party, the licensee, can buy into the project via upfront or milestone payments, but also with increased contribution to the development costs. When negotiating whether the terms are sufficient for the agreed ownership in the project a sound valuation model is useful.

We will in the following describe how valuation helps to find fair license terms when entering co-development agreements.

Co-development models

There are mainly two forms of co-development deals. Either the two partners agree on a certain division of ownership, or they decide that one party gets the rights to commercialise the drug in a certain geographical area, and the other side gets the other geographical rights. Typically, the ownership division applies when it is likely that the project will be licensed at a later point in time. The geographical split usually applies when the two companies are determined to commercialise the drug themselves.

Another reason for co-development deals is the joint origin of a project. Today drug development projects often require various scientific and technological novelties that stem from different companies. If both companies contributed to the origination of the project, then both have from the beginning a stake in the project.

How to set the terms

Negotiating the deal terms is critical in any license agreement. For co-development deals matters complicate a little more because the parties do already have a stake in the project, or do not contribute equally to the project. Often it is unclear whether the upfront and milestone payments and additional

development contributions already justify the agreed ownership in the project.

Typically we have to differentiate between two parts of the agreement. One part comprises the acquisition of the pre-agreed ownership by the licensee (who originally did not own any share in the project). The second part encompasses the contribution to the development costs of the project. Unfortunately, these parts cannot be kept separate. The joining company agrees to one or two upfront and milestone payments and some additional contribution to the development costs. But how can we judge which terms are fair? And what happens if the project will be licensed before the joining company has triggered all additional payments to get the pre-agreed share in the project? In that case the companies would have to define intermediary ownership proportions.

The virtual company model

For the sake of the modelling of such deals Avance came up with the virtual company model™. Upfront and milestone payments as well as development cost contributions translate automatically into change in ownership in the project.

In our model a project corresponds to a virtual company. At the beginning the company that owns the project is the sole shareholder of this virtual company – VirCo. The joining company, Joiner plc

can now participate in VirCo in two different ways, either via direct payments to the originating company or via development cost contributions. Direct payments can be seen as purchases of VirCo shares. If the companies want to develop the project they have to fund VirCo. Each development phase corresponds to a funding round equal to the costs of that phase. If the two companies contribute disproportionately to their share in VirCo this means that one company dilutes the other company. The ownership in the project is now clearly determined by each company's share in VirCo.

If the companies decide to license the project to a third party, typically a multinational pharmaceutical company, then they divide the license revenues between each other according to their ownership in VirCo.

Example

We illustrate such a co-development deal with the example of a preclinical project that is currently 100% owned by Originator Ltd. Joiner plc is interested in taking a 50% share in the project. Both companies envision to out-license the project at the latest after phase II. The companies agreed on the development budget as outlined in table 1.

Table 1: Development budget

In US\$ Mio	preclinical	phase I	phase II
Originator Ltd	-	1	4
Joiner plc	1.5	1.5	4

The goal is that at the start of clinical phase II trials Joiner plc own 50% of the project. So, if they license it then to a pharmaceutical company, they will equally share the license revenues between each other. According to the virtual company model this implies additional payments from Joiner plc to Originator Ltd as in table 2.

Table 2: License terms

In US\$ Mio	preclinical	phase I	phase II
Upfront	1	-	-
Milestone	-	2	3

With the upfront payment of US\$ 1 Mio and with providing all funding for the preclinical phase Joiner plc purchases 26% of the project. The upfront payment alone is worth 12% of the project. The funding for the preclinical phase entitles it to 15% of the newly funded company. Joiner plc therefore owns 15% plus 11% from the upfront payment. Note that Joiner plc diluted its own stake of 12% with the capital increase ($11\% = (100\% - 15\%) * 12\%$). With a milestone of US\$ 2 Mio and US\$ 0.5 Mio more in contribution to the phase I costs Joiner plc increases its stake by another 15% to 41%. At the start of phase II Originator Ltd finally sells the remaining 9% to Joiner plc for US\$ 3 Mio, corresponding to an expected value of the project of US\$ 34 Mio at the beginning of phase II.

Table 3: Calculation

Phase	preclinical	phase I	phase II
Value of project	8.2	16.3	34.3
Upfront/Milestone	1	2	3
As % of value	12%	12%	9%
Pre-money share of Originator	88%	62%	50%
Capital increase	1.5	2.5	8
In% of post-money value	15%	13%	19%

Thereof for Originator	0%	5%	9.5%
Post-money share of Originator	74%	59%	50%

We recommend including a clear rule about who will pay how much in case the actual costs do not exactly match the budgeted costs. This can be done in different ways. For instance it could be specified that one company bears all the excess payments, or that they will be split according to the ownership as determined by the virtual company model. If the preclinical phase finally costs US\$ 2 Mio instead of just US\$ 1.5 Mio, then the not accounted US\$ 0.5 Mio are split 74%-26% between Originator Ltd and Joiner plc. For this, of course, the two companies have to specify the ownership dynamics in the co-development agreement. This way they avoid difficult discussions and subsequent delays.

The above outlined terms are not the only solution for a co-development agreement between the two companies. The following deals would be equally fair. Joiner plc could immediately purchase 50% of the project by paying US\$ 4.1 Mio to Originator Ltd.

Table 4: Immediate 50% Deal

In US\$ Mio	preclinical	phase I	phase II
Costs Originator Ltd	0.75	1.25	4
Costs Joiner plc	0.75	1.25	4
Upfront	4.1	-	-
Milestone	-	-	-

Table 5: Immediate 50% Deal, Calculation

Phase	preclinical	phase I	phase II
Value of project	8.2	16.3	34.3
Upfront/Milestone	4.1	-	-
As % of value	50%	0%	0%
Pre-money share of Originator	50%	50%	50%
Capital increase	1.5	2.5	8
In% of post-money value	15%	13%	19%
Thereof for Originator	7.5%	6.5%	9.5%
Post-money share of Originator	50%	50%	50%

On the other hand Joiner plc could agree to pay all development costs up to phase I and then purchase the remaining part of the project.

Table 6: Complete Funding Deal

In US\$ Mio	preclinical	phase I	phase II
Costs Originator Ltd	-	-	4
Costs Joiner plc	1.5	2.5	4
Upfront	-	-	-
Milestone	-	-	8

Table 7: Complete Funding Deal, Calculation

Phase	preclinical	phase I	phase II
Value of project	8.2	16.3	34.3
Upfront/Milestone	-	-	8
As % of value	0%	0%	0%
Pre-money share of Originator	100%	85%	73%
Capital increase	1.5	2.5	8
In% of post_money value	15%	13%	19%
Thereof for Originator	0%	70%	9.5%
Post-money share of Originator	85%	73%	50%

Conclusion

Co-development deals provide many advantages to the licensor, who reduces his capital needs but keeps a much better upside potential as in the case of a straight license deal. The virtual company model is an easy-to-understand method to determine the contract terms, no matter whether the contributions happen in the form of milestone payments or funding of trials.

In a next newsletter article we will discuss how to set the terms for co-development deals that concern only some geographical rights.

References

The virtual company model™ is explained in detail in the following two publications:

Bogdan B. and Villiger R., "Valuation in Life Sciences. A Practical Guide", second revised and extended edition, Springer Verlag, 334 p..

Villiger R. and Bogdan B., "Deconstructing early-stage contracts", BioPharma Partnering, Scrip Supplement, Winter 2007/8.