

Early-stage contracts with sublicensing clauses

Many biotech companies start as a spin-off from a university. The university typically participates in the success of the company either via an equity participation or a license contract concerning the to-be-developed IP. These early-stage contracts are a challenge for tech transfer officers and biotech entrepreneurs alike. In this article we explain how to structure these contracts.

Early-stage contracts

For most early-stage contracts the licensee, i.e. the license taker, is not necessarily the company ultimately commercialising the project. Often the licensee again licenses the project to a third company that finalises the development and commercialises the project. In drug development these parties are typically academia as the original licensor, biotech as the first licensee, and pharma as the second licensee or the sublicensee. Of course, other constellations are imaginable, a biotech company can license a project to a peer and the peer then to a pharmaceutical company, or the project can pass through more than three companies.

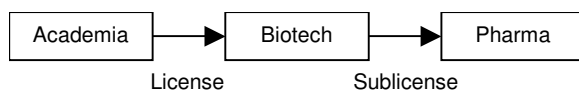


Figure 1: Early-stage project

At the time when biotech wants to license the project again to a pharmaceutical partner the original license contract with the academic institution is the minimum the biotech needs to get out of the negotiations with pharma. It is possible that biotech cannot license the project to terms that are attractive enough given the

liability vis-à-vis its academic partner. The original terms could therefore lead to a dead-lock, leaving both academia and biotech without any future revenues although a partner would be interested in licensing it in. On the other hand, if the project turns out to be better than anticipated, the biotech company can negotiate fantastic terms without academia participating in this upside.

Both situations are unfortunate. If the project is licensable it should be licensed and if the project becomes a blockbuster, then the originator should also participate in this success. In early stage contracts it has become common to include sublicensing terms that work as follows: If the licensee sublicenses the project, then all later payments of the licensee to the licensor will be replaced by a certain part of the payments the licensee receives from the sublicensee. The amount of these payments is defined by means of participation rates that typically vary depending on the stage of the project at sublicensing.

| Sublicensed in | Contract Terms (Milestones and Royalties) | | | | | | |
|----------------|---|------|-----|-----|-----|-----|-------|
| | LO | Prec | CP1 | CP2 | CP3 | NDA | Comm. |
| Lead opt. | | | | | | | |
| Preclinical | | | | | | | |
| Phase I | | | | | | | |
| Phase II | | | | | | | |
| Phase III | | | | | | | |
| Review | | | | | | | |
| Comm. | | | | | | | |

Terms are replaced by a share of the sublicensee's payments depending on the phase of sublicensing.

Biotech pays Academia milestones and royalties as agreed as long as project is not sublicensed.

Figure 2: Contract terms in case of sublicensing

Interestingly, negotiations between academic institutions and biotech companies concentrate often on these participation rates. The sublicense between biotech and pharma is the moment when the biotech's value is determined and it is of utmost importance to biotech to keep as much of the negotiated terms as possible.

Intuitively it is clear that the terms should decrease with continuing contribution of the biotech company to the development of the project. If biotech sublicenses the project immediately after having licensed it from academia then it should pass most of the terms to academia, as it has not contributed much to the project. But if biotech took the project into the clinic and invested a lot of money in it then it seems fair that it can claim a large part of the sublicense terms. A sound model for the site of these participation rates should be very useful. For this reason Avance has developed the virtual company model. This model has already been described in Avance's newsletter Nr. 3 on co-development and also in the book "Valuation in Life Sciences. A Practical Guide". We give here another short description and a practical application to an early-stage contract.

Virtual Company Model

We assume that the project that is to be out-licensed is the sole asset of a virtual company. We will call the company PROJECT. Before the license contract becomes effective, PROJECT is wholly owned by Academia. The main consequence of a license agreement is that the licensee adds a project to his pipeline and the licensor receives money in exchange for the project. A license is therefore very similar to a sale, with the difference that the price for the asset is not paid in full upfront but only in staged payments. Nevertheless, the licensee should still pay the full price if he wants to acquire the full rights to the asset – if the licensee would simply buy the asset instead of licensing it, he would also have to pay the full price and

not only a fraction of it. The licensee, in this case Biotech, will therefore subsequently buy shares of PROJECT to buy rights in the asset, starting with an upfront payment, then milestone payments, and finally royalty payments, until in the end he owns all of PROJECT's shares. The license contract becomes effective with the upfront payment, which the licensor, in our case Biotech, pays. With this upfront payment Biotech buys some shares of PROJECT from Academia, and consequently a part of the asset it is interested in. Biotech now has already an initial stake in PROJECT. We assume that PROJECT conducts the development of the compound and that Biotech should capitalise PROJECT for this purpose. The funding of the first development phase would be equal to a series A investment round with Biotech as the sole investor. In exchange for the investment, Biotech receives shares, which correspond to a capital increase of PROJECT, i.e. to newly issued shares. In the real world Biotech, would conduct and finance the development on its own. In our case it finances the R&D of PROJECT. If the compound successfully passes this phase, then another milestone payment is due. Again, this milestone payment corresponds to an acquisition of PROJECT shares by Biotech from Academia. But now the value of the shares has changed. The shares are more valuable as the success rate of the previous phase is not included in the valuation anymore and the compound is closer to the market, i.e. the cash flows are discounted less. To fund the next phase, PROJECT conducts another financing round, a Series B round. Again, Biotech acts as the sole investor.

These modifications of ownership with acquisition of shares due to milestone payments and dilution due to capitalisation for phase costs continue until the compound reaches the market.

Once the compound is on the market and the launch milestone is paid, we have to set the royalties as dividends for Academia from the profit that PROJECT makes. Biotech and Academia both hold shares in PROJECT. We can assume that all yearly profits will be immediately paid out to the shareholders in form of dividends. Academia can claim the portion of these dividends according to its share in PROJECT. In the following we will illustrate how to apply this method to the problem of sublicensing.

Example

Academia and biotech have already agreed on the license contract exhibited below for a project that now first requires some more chemistry in order to prepare it for the clinical phases, i.e. it is in lead optimisation phase.

Table 1: Early-stage license contract

| | In US\$ Mio |
|-------------|-------------|
| Upfront | 0.15 |
| Preclinical | 0.2 |
| Phase I | 0.3 |
| Phase II | 0.5 |
| Phase III | 1 |
| Filing | 2 |
| Approval | 4 |
| Royalties | 3% |

It is relatively clear that biotech expects high peak sales, let say in the order of at least US\$ 500 Mio, otherwise it would hardly try to license the project in such an early stage. We expect that

the patent protected time lasts until 12 years after launch and that costs, timelines, and success rates are as displayed in table 2.

Table 2: Valuation Assumptions

| | Lead Opt | Preclinical | Phase I | Phase II | Phase III | Review |
|------------------|----------|-------------|---------|----------|-----------|--------|
| Costs (US\$ Mio) | 1 | 2 | 4 | 10 | 60 | 3 |
| Success Rate | 70% | 65% | 80% | 40% | 65% | 85% |
| Duration (years) | 1 | 1.5 | 1.5 | 2 | 3 | 1.5 |

We assume patent protection for 12 years after launch and peak sales of US\$ 500 Mio reached after 7 years. COGS and marketing and sales expenses amount to 35% of sales.

With these valuation parameters Biotech achieves a risk adjusted IRR of 22.72%. Using this 22.72% as discount rate and valuing PROJECT at the various stages, we get the following:

Table 3: Value of PROJECT

| | |
|-------------|-------|
| Discovery | 0.9 |
| Preclinical | 3.4 |
| Phase I | 11.2 |
| Phase II | 25.9 |
| Phase III | 135.1 |
| Review | 554.8 |
| Market | 892.1 |

Applying the virtual company model we can now calculate how much academia holds of PROJECT at the beginning of a stage, after biotech's purchase of a share package via a milestone payment (or upfront payment), and after the dilution due to biotech's funding of the next phase. We receive the following participations:

Table 4: Sublicensing Terms

| Phase | Share before | Share after milestone | Share after dilution |
|-------------|--------------|-----------------------|----------------------|
| Discovery | 100.0% | 83.7% | 40.1% |
| Preclinical | 40.1% | 34.2% | 21.5% |
| Phase I | 21.5% | 18.8% | 13.9% |
| Phase II | 13.9% | 11.9% | 8.6% |
| Phase III | 8.6% | 7.9% | 5.4% |
| Review | 5.4% | 5.1% | 5.1% |
| Market | 5.1% | 4.5% | 4.5% |

The US\$ 0.15 Mio upfront payment corresponds to $0.15/0.9=16\%$ of PROJECT, therefore Biotech purchases with the upfront payment 16% of PROJECT. Academia, left with 84% of PROJECT, now gets diluted due to biotech's funding of the discovery phase. Biotech injects US\$ 1 Mio in PROJECT, Academia's share therefore becomes $(84\%*0.9)/(0.9+1)=0.8/1.9=40\%$.

The sublicensing terms now are the terms as displayed in table 5. They assume, that the milestone of the coming round has not yet been paid.

Table 5: Sublicensing Terms

| | |
|-------------|-------|
| Discovery | 40.0% |
| Preclinical | 21.5% |
| Phase I | 14.0% |
| Phase II | 8.5% |
| Phase III | 5.5% |
| Review | 5.0% |
| Market | 4.5% |

So, if Biotech for example sublicenses the project at IND, i.e. still before having paid Academia the milestone for phase 1, then Academia would receive in the future 21.5% of what Biotech receives from the sublicensee in terms of upfront, milestones, and royalties.

Conclusion

By means of the virtual company model the previously hard-to-quantify sublicensing terms, that are so important to biotech, become a straightforward consequence of the deal terms. We have seen that discussions become less emotional and focus on well-defined valuation parameters like costs, success rates, or peak sales.

Should you have trouble in designing an Excel sheet to calculate sublicensing and deal terms you can order it in our webshop www.avance.ch/shop/excels.html.