once it executes the option and takes on full responsibility of the development and commercialisation of the project. Unfortunately a license contract is not just as easy to translate in value like a strike of a normal financial option (a strike of USD 100 is worth USD 100, not too difficult, right?). And moreover, it is much more difficult to translate increased value of a drug development asset into an improvement of license terms, because all license terms (upfront, milestones, and royalties) can change. It is already a small challenge to define the different values of the drug development project and the corresponding probability distribution.

Using the value share approach

The value share approach is of some help to us. Assuming that at the point of execution we can calculate the value of the project for any set of assumptions, we can also calculate the value of a fair license contract; it is simply a fixed percentage of the project value; depending on the stage of the project at the time of execution. Of course, we can also calculate the value of the predetermined license contract for each set of assumptions. The value of the option agreement for the licensee at that point is then the difference between the value of the fair license contract and the value of the predetermined license contract. If this value is positive, i.e. the licensee gets the project cheaper than if he would have to negotiate the terms then, then he executes the option. Otherwise he either declines the option or starts renegotiating the terms.

But knowing the value of the option at the moment of execution allows us calculating the value of the option at the time of closing the option agreement. We simply need to risk-adjust and discount all option values (the risk adjusting involves, first, the probability that a specific set of assumptions occurs, and second, that the project reaches that stage of development (i.e. the success rate)).

Using the real option approach

In fact, the calculation of the option fee is one of the better applications of the real option approach in biotech valuation. While we have mentioned different "sets of assumptions" we actually meant different sales assumptions. The binomial tree method is very practical to define various sales estimate scenarios at execution of the option. Starting with today's best guess of the sales forecast we can then chose the volatility such that we get a reasonable range of scenarios at time of execution. For each node of the binomial tree at time of execution we can then calculate the value of the fair license contract and the value of the predetermined license contract. Knowing these we can go back step-wise; exactly like in real options valuation. Finally, we can retrieve the value of the option fee at the root node.

Example

Let's play this through with an example. Assume a phase 2 drug with the following assumptions:

Table 1: Assumptions

	Costs (USD mn)	Success Rate	Duration (Years)
Phase 2	15	40%	2
Phase 3	60	60%	3
Review	5	85%	1

Peak Sales	USD 750 mn
Launch Costs	USD 100 mn
COGS+M&S	35% of revenues

A pharma company would like to enter into an option agreement paying an option fee and possibly executing the option to license the drug at predetermined terms after the ongoing phase 2. This would then correspond to a phase 3 deal and we assume that for phase 3 deals a value share of 50%-50% is common. The proposed license deal goes as follows:

Table 2: License Deal (in USD mn)

Upfront	Filing	Approval	Royalties
50	60	120	18%

This deal corresponds to 51% of the whole project value at start of phase 3 and peak sales assumptions of USD750 mn.

If we span a tree with 6 time steps and a volatility of 50% we receive 7 possible scenarios at time of execution, ranging from peak sales estimates of USD 276 mn up to USD 2,039 mn. The volatility can be chosen such that this range corresponds to a realistic span of sales assumptions given that today the results of phase 2 are not yet known. For each of the seven nodes we can calculate the value of the full project. 50% of that value would correspond to the value of a fair license deal, if negotiated only once the phase 2 results are known. And we can also calculate the value of the license deal as displayed in table 2. In the middle node (sales assumptions of USD 750 mn) the option is slightly out of the money (the predetermined terms amount to 51% of the value, a fair deal only to 50%). This means that if after phase 2 the sales potential hasn't improved, then the option has no value. But in the best scenario (USD 2,039 mn) the licensee would save USD 260 mn in value. Calculating back the tree (accounting for the success rate of phase 2, the discounting for each time step, and taking each time the probability-weighted value of the upper and lower scenario) we receive a value of the option of USD 7 mn.

Discussion

An increase of USD 1 mn in the option fee requires in our example a reduction of the upfront payment by USD 9 mn, or, e.g., an increase of the volatility to 56%. It becomes clear that the volatility is a critical parameter, even though it is difficult to estimate. Nevertheless, a graphical representation as in figure 2 allows determining the volatility in an intuitive way. Clearly, the greater the volatility, the wider is the spread of the different scenarios. With a 75% volatility the calculation even allows for a USD 3.3 bn sales scenario, even though only with 1% probability.

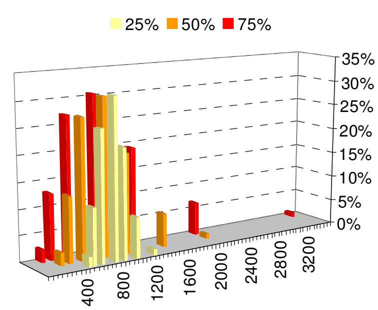

Figure 2: Sales estimate scenarios depending on the volatility.

Figure 3 displays the sensitivity of the option fee to the volatility.

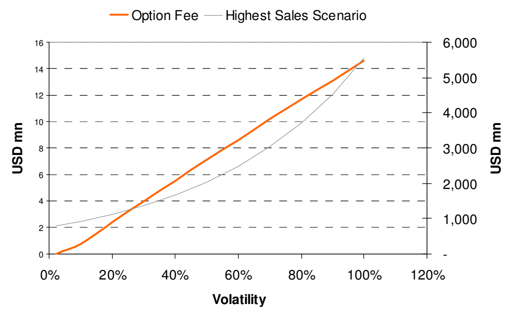

Figure 3: Sensitivity of option fee to volatility.

Note that the highest sales scenario is each time only probability-weighted with 1%, so rather unlikely. It is therefore completely reasonable to use high volatilities of 50%-100% in this particular setting. Of course, one is free to use any other distribution of sales estimate scenarios; not necessarily the ones implied by the binomial tree. The binomial tree just provides a smooth and tailed distribution that doesn't look all wrong. But depending on the project and the trial design it might be a good idea to assume a few specific scenarios, e.g. where efficacy is reached in different patient groups, clearly identifiable with biomarkers. Each of those scenarios gives rise to its own sales estimate, considering the competitive environment in each of those patient groups. Maybe the licensee is only interested in the project if one of the larger patient groups is treatable with the drug. In that case the license contract should be aligned with that scenario (so rather high), even though this means that on average the license contract is clearly out-of-the-money.

What is the value to the biotech company?

The value of the whole option agreement is slightly more complicated because of several reasons. First, the discussed license contract is only applicable in the scenarios when the pharmaceutical company triggers the option. We therefore need to define some sort of salvation value for the remaining scenarios (i.e. for the scenarios where the options ends up out-of-the money). This salvation value can be either that the biotech company decides to go ahead on its own, or licenses the project to cheaper terms, or stops it altogether. Second, we need to account then for the time between now and the license contract, including the success fee to survive until then, the costs of R&D until then, but also the option fee. This is typically done in the binomial tree, very much like a real option calculation. The main difficulty certainly remains the definition of the salvation value at the end-nodes where the option is not triggered.