Early Stage Valuation

Early stage valuation of drug development is complicated and often considered as being unnecessary. Standard valuation methods like rNPV are - if not properly applied - not useful for this purpose and often lead to negative numbers. Therefore, many companies do not even value projects before entering clinical phase 1. However, there are situations when valuations are necessary at very early stages in drug development, e.g. technology transfer licensing between universities/research institutes and biotech/pharma.

There are three critical parameters to consider when performing early stage valuation:

1. Success rates
2. Drug development costs
3. Sales potential

Success rates

Success rates for clinical trials are readily availably [1-4]. There are few sources for the phases before clinical trials. Most companies involved in drug development collaborate with CMR international, submitting their early stage numbers. Unfortunately, CMR is not an open source and therefore not accessible to all. A good publication giving an idea on the numbers to be used is „Rethinking innovation in Pharmaceutical R&D" [5].

Drug development costs

Costs, especially for clinical trials depend on the company conducting the trials. A rule of thumb is that clinical trials performed by pharma cost five times more than those performed by biotech. This means that numbers published by DiMasi do not apply for small biotech companies one on one. However, pharmaceutical companies cover more indications in their trials than biotech companies that conduct the minimum program. Furthermore, early stage valuations often incorporate future license contracts. In that case, costs have to be adjusted for the respective company.

Phase	Time	Cost	Success rate
Discovery	**1-2 years**	**$1-3 mio**	**50%**
Preclinical			
In-vitro	1 year	$1 mio	67%
In-vivo	1-2 years	$1-2 mio	75%
Toxicology	1-2 years	$1-2 mio	80%
Total	**3-5 years**	**$3-5 mio**	**40%**
CMC preclinical		**$1-2 mio**	
IND	**3-6 months**	**$0.5-$1 mio**	**67%**
Clinicals			
Phase 1	1-2 years	$1-3 mio	50%
Phase 2	2-3 years	$3-6 mio	62%
Phase 3	3-4 years	$10-$20 mio	93%
Total clinical	**6-9 years**	**$14-$29 mio**	**29%**
CMC NDA		**$2-$4 mio**	**93**
NDA			
preparation	0.5-1 year	$1-2 mio	100%
review	1-2 years	$1-2 mio	75%
Total Nda	**1.5-3 years**	**$2-$4 mio**	**75%**
Total	**12-21.5 years**	**$23.5-$48 mio**	**1%**

Sales potential

It is very hard to predict peak sales for a compound several years from now. There are two basic approaches to calculate future peak sales of a compound: bottom-up (patient_number*price_per_unit*number_of_units_per_year*margin) or top-down (% of a defined market). Often it is not clear in which indication the drug will be effective, we suggest to use the most-likely drug sales of the disease category the drug best fits in, e.g. CNS, or more closely epilepsy (cf. leaflet on peak sales). Using most likely peak sales permits the application of rNPV for the valuation, as the sales are conditioned to reach market (cf. leaflet on success rates).

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