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Biotechnology Valuation

NPV EVOLUTION ALONG R&D PROJECTS

SUMMARY

Most biotech discoveries/products are associated with expensive and long development timelines, high product risks, and a limited product life cycle in the same way that most other commercialized products do. The risk-adjusted NPV (rNPV), otherwise known as the expected NPV, is the most theoretically rigorous way to value R&D projects including new drugs in biotech/pharma pipelines.

Approximate NPV tables for products at various stages of development (R&D -> Registration) are included with standardized assumptions. The standardized models presented are based on Bennet et al., 2004, Biotechnology valuation – An investor´s guide (ING Financial Markets Publication).

About the author

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NPV EVOLUTION – STANDARDISED MODELS[1]

The risk-adjusted NPV (rNPV), otherwise known as the expected NPV, is the most theoretically rigorous way to value R&D projects including new drugs in biotech/pharma pipelines. The method considers all of the inbound and outgoing cash flows, including sales or royalty revenues, milestones, R&D and clinical trial expenses, cost of goods sold, SG&A together with estimated product risks and the opportunity cost of capital. Here is standard NPV tables to estimate future potential drug products at various stages of development with respect to projected peak sales and royalty rate presented.

Note: NPV valuations of potential biotech products are demanding due to the long and uncertain product development schemes and typically based on a number of estimates and assumption. Sensitivity and scenario analysis should therefore be utilized to assess the changes in valuation due to individual assumptions and assess the impact of various arrangements of assumptions. Thus, the standard NPV models should only serve as guidelines. Particular product characteristics associated with a new product would needed to be included in any thorough analysis (specific clinical risks or safeties, specific regulatory risks or safeties, specific molecular risks or safeties, specific sales forecasting risks or safeties). The standardized models (Table 1-5 and Fig. 1) are based on Bennet et al., 2004; Biotechnology valuation – An investor´s guide.

ASSUMPTIONS FOR THE NPV STANDARD MODELS

Standardised NPV models are included in Table 1-5 and Fig. 1. The particular assumptions underlying the models are:

- No milestones or upfront payments are included
- Development timelines (entering the phase) and success rates for a molecule to marketing approval:
  - Hit-to lead and lead generation: 18 months (0,01%)
  - Lead optimization: 30 months (0,02%)
  - Early pre-clinical: 12 months (0,4%)
  - Late pre-clinical: 12 months (5%)
  - Phase I: 12 months (10%)
  - Phase II: 12 months (30%)
  - Phase III: 24 months (70%)
  - Registration: 12 months
- Discount rate (13%)
- Use of typical product life cycle with standard growth curve and peak sales at the 10th year after launch.
- Revenues derived exclusively on partnered royalties (i.e. no COGS, marketing costs etc.).
- Overhead on 30% from the combined revenue stream (R&D and G&A) and tax at 30%

Table 1. NPV evolution of a US$ 500M estimated peak sale pharmaceutical product with respect to development phase and royalty rate. Example: A NME with estimated peak sales of 500M $US will have a rNPV of 15,8M $US when entering Phase I clinical testing. The particular product risks associated with the NME if any would needed to be included in any thorough analysis (specific clinical risks, specific regulatory risks, specific molecular risks, specific sales forecasting risks)

NPV (M US$)	5%	10%	20%	30%
NPV at lead generation	0,04	0,08	0,16	0,24
NPV at lead optimisation	0,98	1,96	3,92	5,88
NPV at early pre-clinical	2,84	5,68	11,36	17,04
NPV at late pre-clinical	3,94	7,88	15,76	23,64
NPV at Phase I	7,88	15,76	31,52	47,28
PV at Phase II	26,73	53,46	106,92	160,38
NPV at Phase III	70,47	140,94	281,88	422,82
NPV at Registration	115,69	231,38	462,76	694,14

Fig 1. NPV evolution of a US$ 500M estimated peak sale pharmaceutical product with respect to development phase and royalty rate. Same data as presented in Table 1 illustrated graphically.

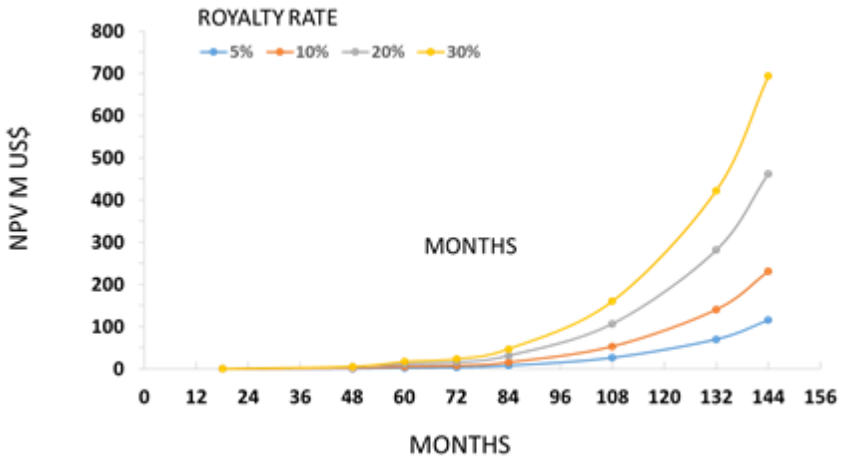


Table 2 to 5. Standardised NPV´s for drug discovery and drug development projects. NPV for early-stage R&D drug discovery (lead optimization), late pre-clinical development, Phase I+II candidates in clinical development with respect to projected peak sale and royalty rate.

Table 2. Standardised NPV´s for candidates in early-stage R&D drug discovery (lead optimization).

NPV (M US$)		5%	10%	20%	30%
PEAK SALES (M US$)	***50***	0,09	0,17	0,35	0,52
	100	0,17	0,35	0,70	1,04
	200	0,35	0,70	1,39	2,09
	300	0,52	1,04	2,09	3,13
	400	0,70	1,39	2,78	4,18
	500	0,87	1,74	3,48	5,22
	600	1,04	2,09	4,18	6,26
	700	1,22	2,44	4,87	7,31
	800	1,39	2,78	5,57	8,35
	900	1,57	3,13	6,26	9,40
	1000	1,74	3,48	6,96	10,44

NPV in millions of US$ with respect to expected peak sales and royalty rate.

Table 3. Standardised NPV´s for candidates in Preclinical development (late pre-clinical development).

NPV (M US$)		5%	10%	20%	30%
PEAK SALES (M US$)	***50***	0,4	0,8	1,6	2,4
	100	0,8	1,6	3,2	4,7
	200	1,6	3,2	6,3	9,5
	300	2,4	4,7	9,5	14,2
	400	3,2	6,3	12,6	19,0
	500	4,0	7,9	15,8	23,7
	600	4,7	9,5	19,0	28,4
	700	5,5	11,1	22,1	33,2
	800	6,3	12,6	25,3	37,9
	900	7,1	14,2	28,4	42,7
	1000	7,9	15,8	31,6	47,4

NPV in millions of US$ with respect to expected peak sales and royalty rate.

Table 4. Standardised NPV´s for candidates in clinical development (Phase I).

NPV (M US$)		5%	10%	20%	30%
PEAK SALES (M US$)	***50***	0,8	1,6	3,2	4,7
	100	1,6	3,2	6,3	9,5
	200	3,2	6,3	12,6	18,9
	300	4,7	9,5	18,9	28,4
	400	6,3	12,6	25,2	37,8
	500	7,9	15,8	31,5	47,3
	600	9,5	18,9	37,8	56,8
	700	11,0	22,1	44,2	66,2
	800	12,6	25,2	50,5	75,7
	900	14,2	28,4	56,8	85,2
	1000	15,8	31,5	63,1	94,6

NPV in millions of US$ with respect to expected peak sales and royalty rate.

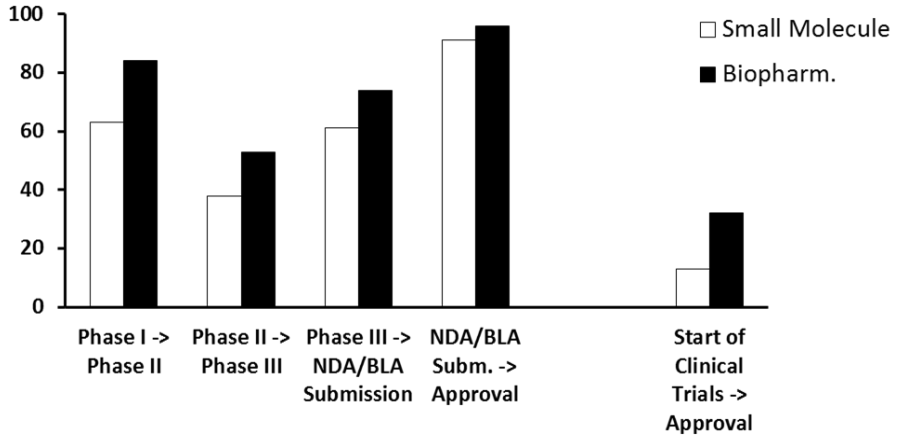
Table 5. Standardised NPV´s for candidates in clinical development (Phase II).

NPV (M US$)		5%	10%	20%	30%
PEAK SALES (M US$)	***50***	2,7	5,3	10,7	16,0
	100	5,3	10,7	21,4	32,1
	200	10,7	21,4	42,8	64,1
	300	16,0	32,1	64,1	96,2
	400	21,4	42,8	85,5	128,3
	500	26,7	53,5	106,9	160,4
	600	32,1	64,1	128,3	192,4
	700	37,4	74,8	149,7	224,5
	800	42,8	85,5	171,0	256,6
	900	48,1	96,2	192,4	288,6
	1000	53,5	106,9	213,8	320,7

NPV in millions of US$ with respect to expected peak sales and royalty rate.

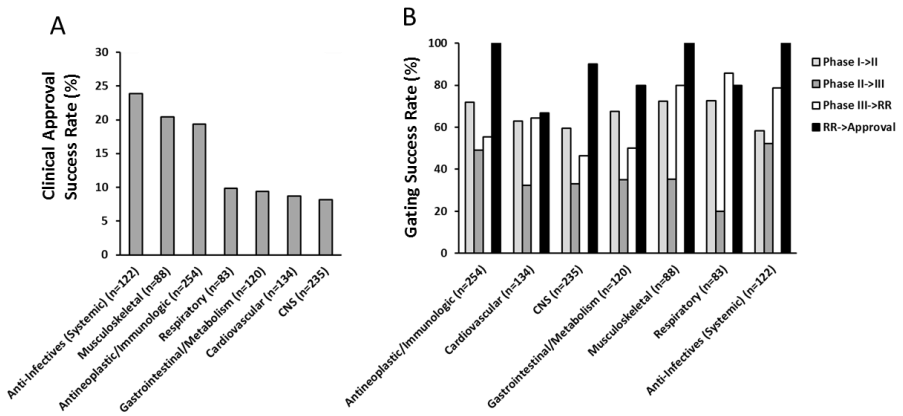
RISKS – AT WHAT DEVELOPMENT STAGES ARE THE MAJOR ATTRITION RISKS?

Of course, a major risk associated with any discovery/development program is associated with development of the technology (development of the final molecule etc.) If an NME´s finally succeeds in entering clinical trials, about 20% of these actually succeed in getting marketing approval (see figure below). The success rate seems slightly lower for traditional small molecule pharmaceuticals vs. large biological molecules (for instance recombinant proteins) perhaps indicating a future trend in drug discovery/drug development.



Success rate for small+large molecules for Phase I->III, NDA and final approval. FIgure made with published data from Kaitin and DiMasi, 2011.

Importantly, the success rates vary with the indication/market (see figure). Thus, if completely based on chance, it will require better data to convince potential investors to Invest in new Development of new cardiovascular therapies. However, a smaller chance for passing the clinical trial efficacy, toxicity studies etc. might be offset by addressing a larger market etc.



RESOURCES, REFERENCES AND KEY LITTERATURE*

ONLINE RESOURCES

The Tufts Center for the Study of Drug Development - (Academic, non-profit research group at Tufts University in Boston, Massachusetts). The center also makes "Outlook reports" which highlights their wiev on the near-term pharmaceutical and biopharmaceutical development trends. The outlook is available through email here.

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