Financial Aspects of Licensing

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AGENDA

- **Deal making: the economic backbone of companies**
- An introduction to valuation and the theory of net present value calculation
- Advanced methods of valuation
- Practical considerations: numbers, sources and markets
- Case studies: How to divide the value
- Conclusion

Biochem-Glaxo Wellcome deal

In 1990, the Canadian biotech company BiochemPharma and GlaxoWellcome signed an early-stage licensing deal regarding the anti-HIV drug 3TC.

Glaxo paid down payments of $1.7 million, research fees of $2.6 million a year and a total of $11 million in milestones.

In addition, the biotech-company received royalties of 13% on net sales.

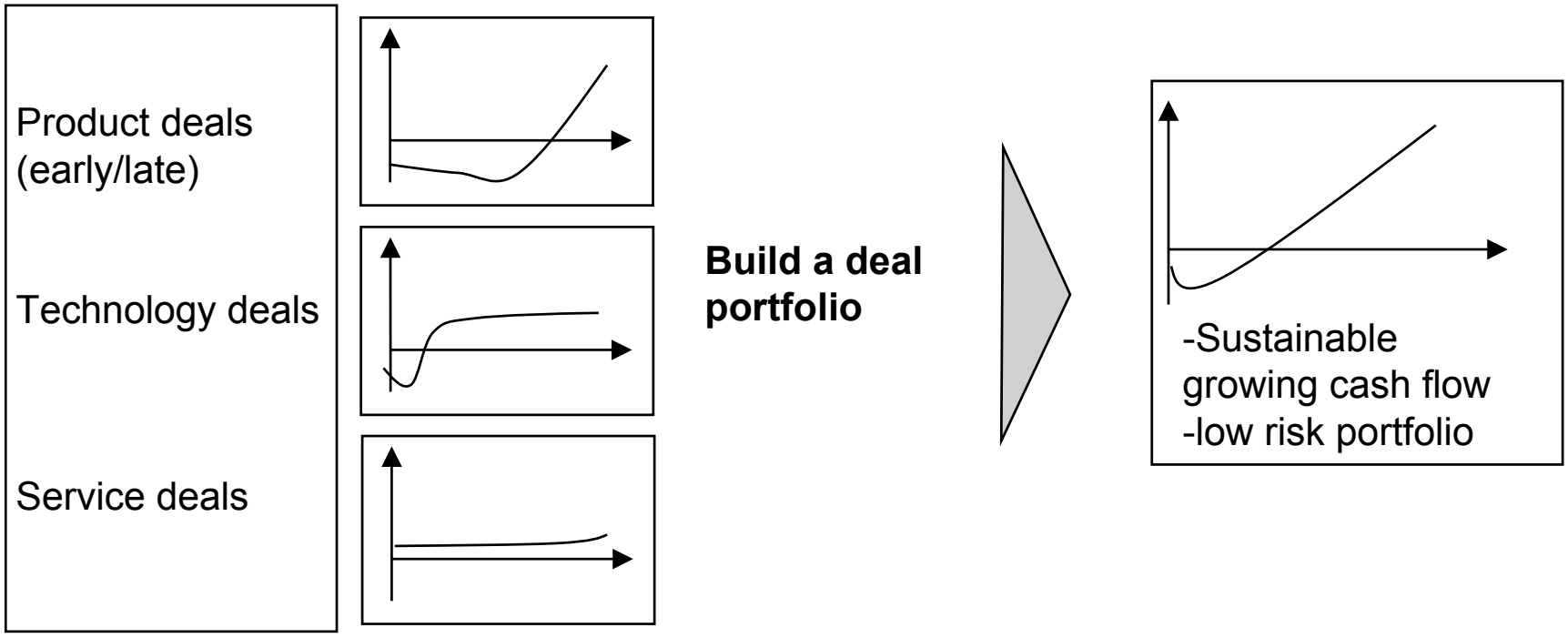
In retrospective, for both companies, it was a successful deal.

Nevertheless, the question remains:

Was it a fair deal and how can you derive the numbers?

Deal Portfolio Secures the Survival of Biotech-Companies

For smaller biotechs (but also for bigger companies), it is important to secure a steady cash flow. Sometimes, higher upside potentials are neglected in exchange to earlier cash. Ideally, a company aims to use the assets to **maximize value creation** and yet achieve an **equilibrated cash inflow.**



Besides financial aspects, access to know-how, patents, data or markets may play a decisive role

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“Deal”-Structures in the Pharmaceutical Industry

Type of deals				Characteristics
	Equity deals	M&A		• Single entity formed by combination of 2 companies • One set of shareholders
		Joint venture		• Two or more companies set up a third jointly owned organization by asset/equity contributions
	Non-equity deals	Licensing deals	Co-development	• Two companies jointly perform research or one company pay another to perform it
			Straight licensing	• Marketing or other commercial rights are handed from one company to another
			Co-promotion	• Two or more companies agree to promote a product in the same territory but under a single trade name
			Co-marketing	• Two or more companies agree to promote a product in the same territory but under a different trade name
		Non licensing deals	Product swaps	• Exchange of product rights between companies
			Product acquisitions	• One party buys all rights to a product for a particular price • The former owner gives up all commercial rights including patent rights

Today`s focus

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(Financial) objectives of licencee and licencor

Licencee	Licensor
•Slow cash/late investments •risk avoidance/late deal •low license fees /royalties •product ownership •exclusivity	•Fast cash (recover investments) •high license fees/royalties •keep ownership •risk sharing/early deal

Find acceptable compromizes, that motivate both parties to work together
Win-win situations are possible

Source: Modified from R. Davies

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Valuation: Why and How?

Goal: Provide the manager with an objective basis for decisions with financial impact on the company

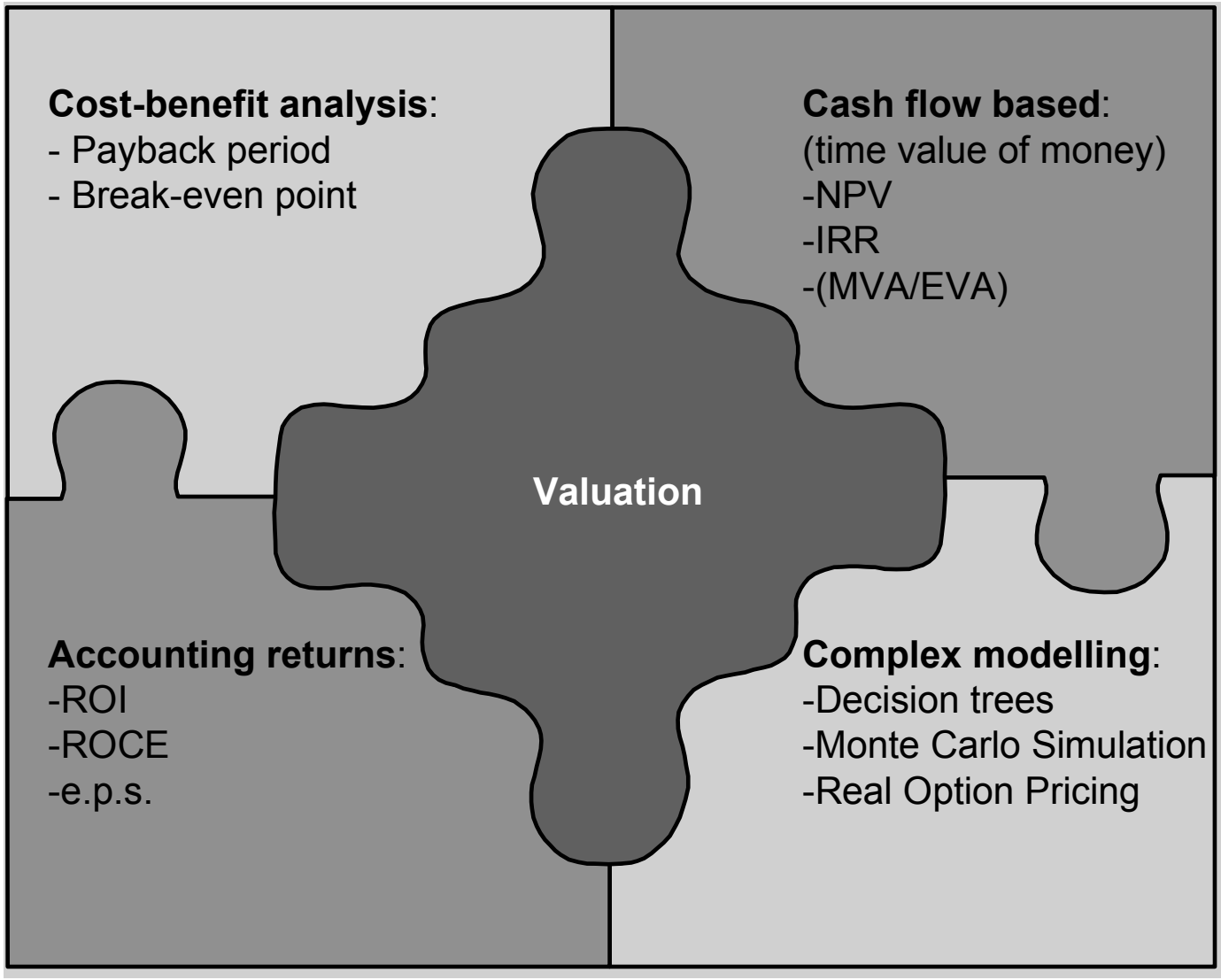
Measure is the alteration of the **value of the company** by the decision (and not the profit)

A project can conceptually be subdivided in a suite of cash-flows, each contributing to the return on investment of the project. Hence, on R + D project translates into an investment aimed to pay interest on the capital.

The required minimum rate of interest depends on the risk of the project an on the cost of capital.

This static point of view of the „**discounted cash flow**“ bond-model does not always depict a realistic case in which degrees of freedom for later revisions exist. More complex methods, based on this model, exist in order to take into consideration the managerial flexibility.

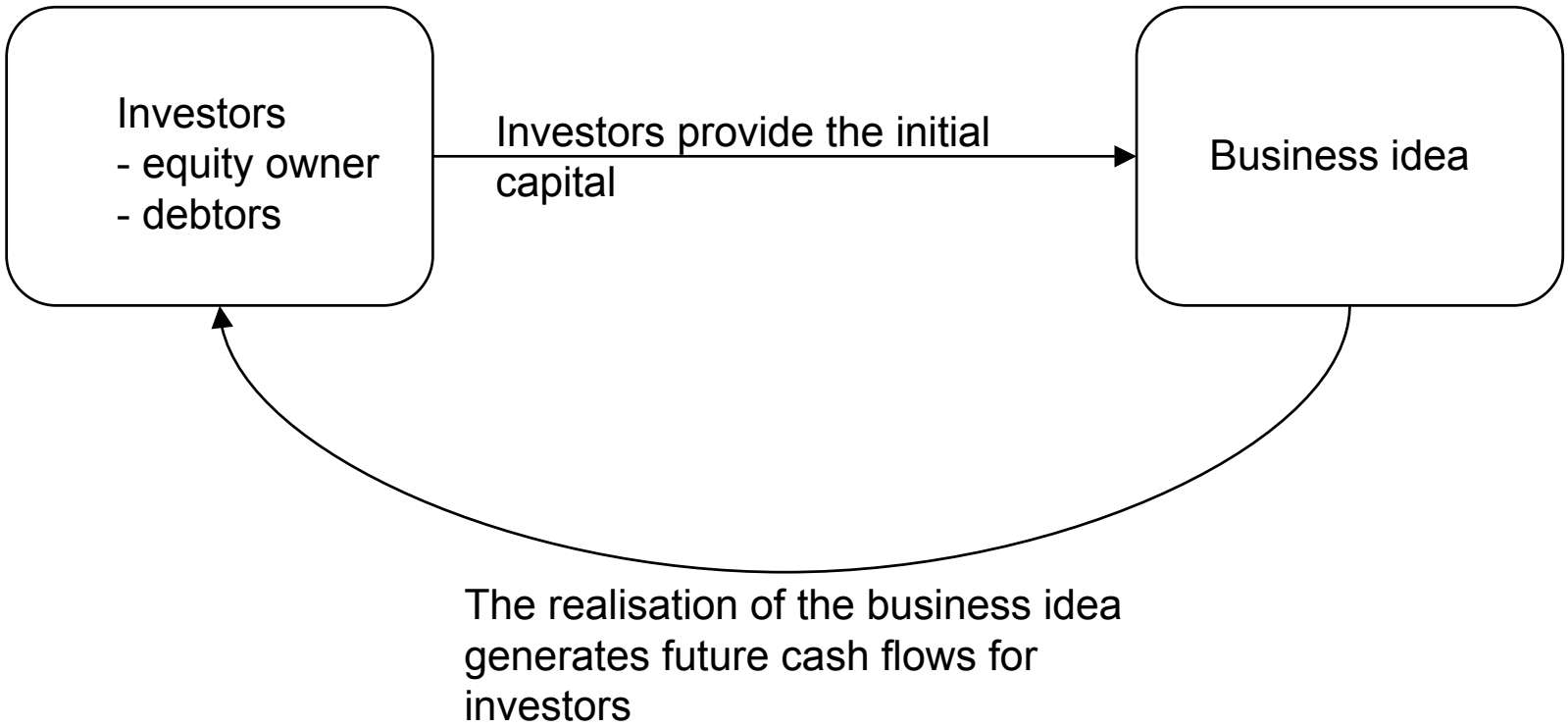
Measures of Profitability/Value-Creation



Primarily used in modern valuation

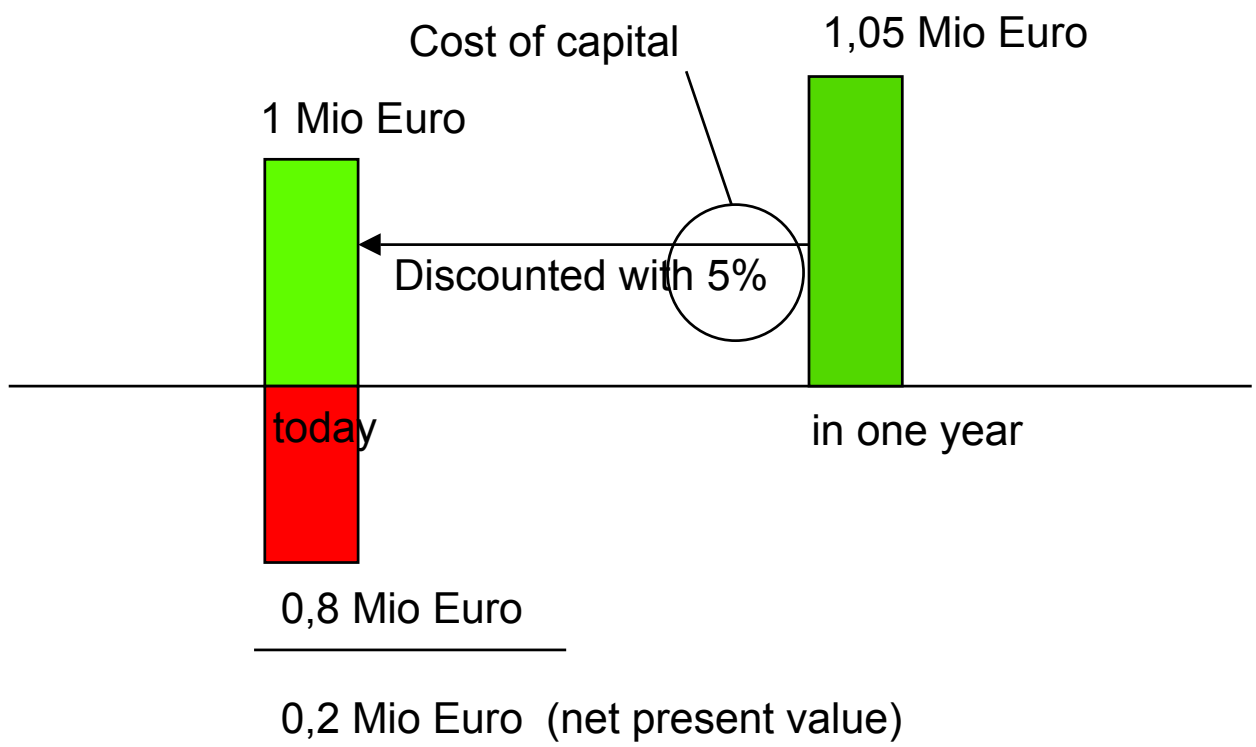
Calculation of Net Present Values: Why Cash-Flow and not Income?

Only cash matters for debtors and investors who paid themselves cash. Accounting numbers are not relevant.



Interest Rates

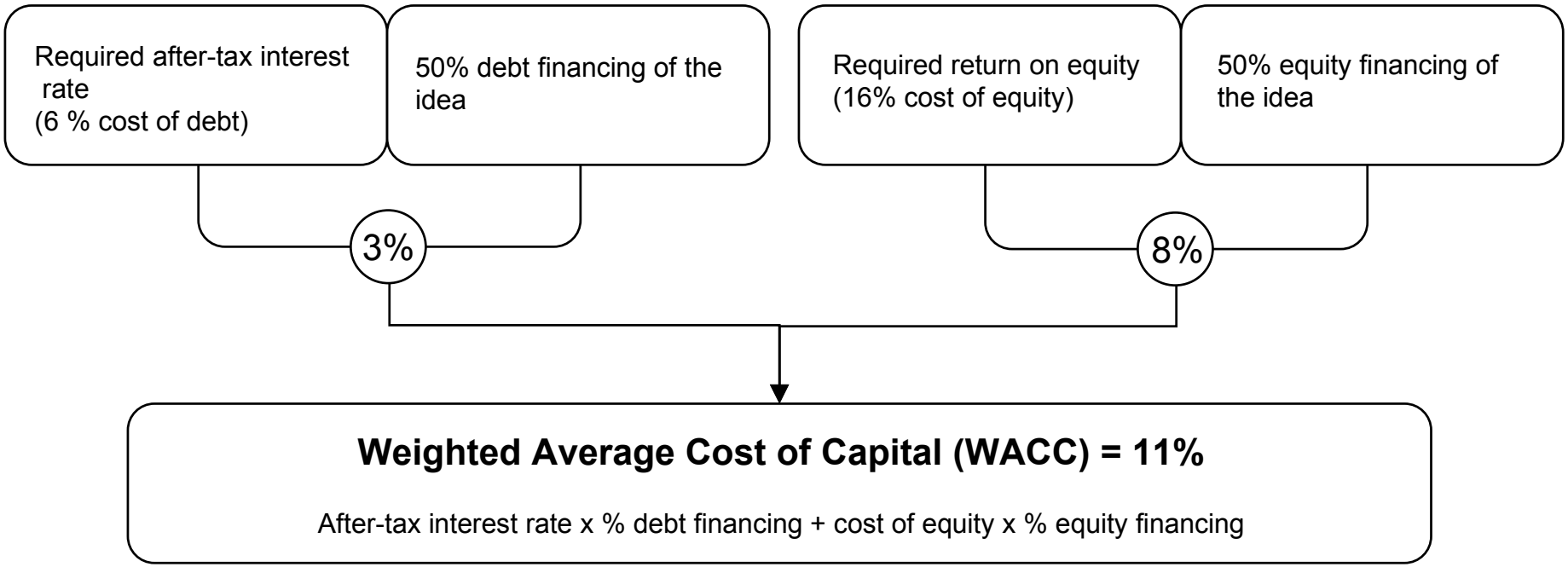
The suitable interest rate of a business idea corresponds to the cost of capital of this idea.



Net present value = - Initial investment + present value of the cash-flow of the project

Cost of Capital

The financing costs of a business idea equal to the weighted average cost of capital:
A company has got two main sources of financing: debt and equity



After-tax interest rate = interest rate * (1-tax rate); f. ex.: Z = 8,6%, T = 30%, After-tax interest rate = 6%; Interest payments are tax-deductible and can be reduced by the tax rate.

How to calculate the two components of the cost of capital?

Cost of debt: Every loan to a company specifies an interest rate.
The cost of debt are simply the weighted average of these interest rates.

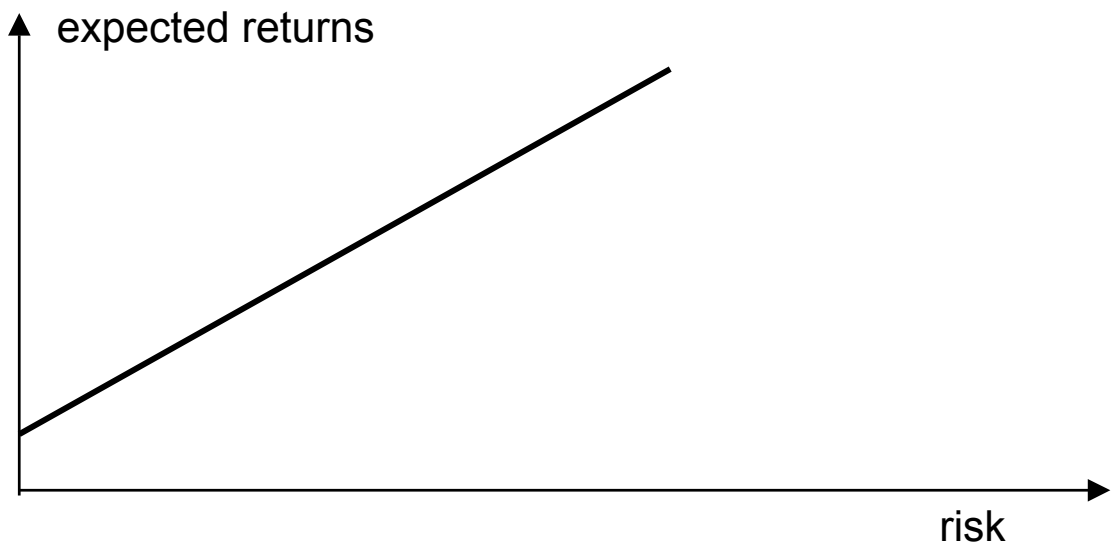
Example: A company signed at different times 3 loans:
100.000 Euro, 6 %, 4 years
150.000 Euro, 7,5 %, 10 years
250.000 Euro, 7 %, 3 years

The resulting cost of debt calculates:
100.000/500.000 * 6% + 150.000/500.000 * 7,5% + 250.000/500.000 * 7% = 6,95%

Unfortunately, for equity, there is no similar contract on return expectations!

How to Deduct the Cost of Equity?

Equity (including retained earning) is not free of charge: A shareholder (= owner) expects a return exceeding the cost of debt because he carries a higher risk. He carries the entire business risk and may, in case of bankruptcy, lose his investment.
Generally speaking: The higher the risk, the higher the expected return. Investors are „**risk averse**“, meaning they avoid the risk of losses without the promises of higher returns. The cost of equity depends both on the industry and on the solidity of the company.



How to Find the Right Discount Factor

The **threshold to invest** can be calculated in a two-step method: 1. Cost of equity (r) and 2. WACC. For all projects of one company, the same hurdle rate r (discount factor) ought to be applied.

1.) The Capital asset pricing model calculates the **cost of equity capital**:

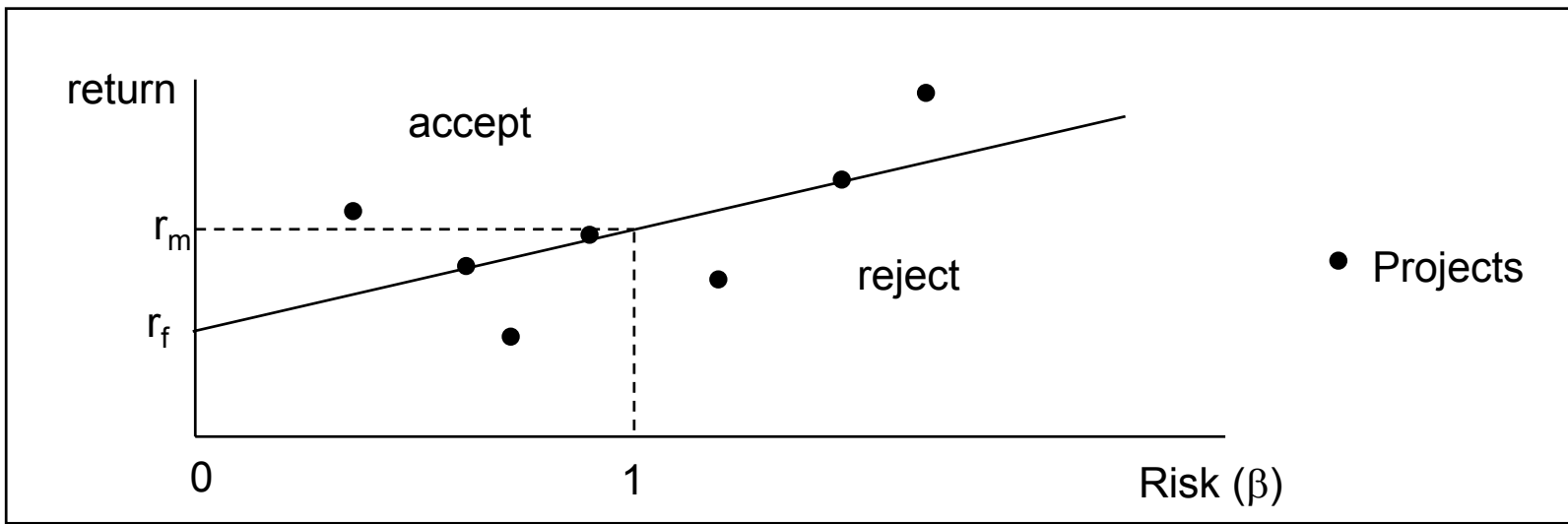
$$\mathbf{r = r_f + \beta(r_m - r_f)}$$

r_f = risk-free rate (Government Treasury bills): 5 - 6 % (includes inflation)

r_m = market return (f. ex. Dow Jones average over 50 years)

$(r_m - r_f)$: expected market premium: usual value: 8.4%

β: risk factor (usually between 0.5 and 2.5), calculated or derived from market proxies



R Depends on the Business and the Companies Financing

Beta values are published by rating agencies (Standard and Poor, Moody) or can be calculated from historical data (stock yield).

Examples:	r(Genzyme):	24,4%
	r(Biogen):	24,5%
	r(Merck):	14,2%
	r(Pfizer):	15,7%
	r(Syntex):	19,1%
	r(EliLilly):	17,6%
	r(SKB):	14,9%
	r(VCs):	~30%
	r(Pharmaceutical industry average):	**15,4%**

i.e. for most Biotech companies, the β-factor (risk factor) is higher than for average portfolios.

Source: Brealey and Myers: Principles in corporate finance

Putting everything together: Calculation of the WACC

After the determination of the components of the cost of capital, the weighted average needs to be calculated.

WACC = r_{debt}*debt/(debt+equity) + r_{equity}*equity/(debt + equity)

$\beta_{portfolio} = \beta_{debt}$*debt/(debt+equity) + β_{equity}*equity/(debt + equity)

Equity capital (higher risk) is more expensive (higher r) than debt financing, but debt need to be served first and continuously (cost depends on financing terms).

Example: WACC (SchwarzPharma): 10 %
WACC (GlaxoWellcome): 12,5 %

The WACC is an important determinant in the calculation of profitability: It represents the **hurdle rate** to start of stop a project (regain the cost of capital or not). The WACC is used in the calculations of the net present value (NPV) as the **discounting factor** and is the same for all projects within a company (comparative prioritisation of different projects).

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Net present value: formula

In principle, reversed interest rate/annuity calculation:

Interest yield: Future value = present value * $(1+\text{Interest rate})^t$

Discounting: present value = future value / $(1 + \text{Interest rate})^t$

$PV = FV/(1+R)^t$ PV = Present value; FV = Future value, R = discount rate;

The future values correspond to the future cash-flows.
The value of the project is the sum of the PVs of the future/annual cash-flows:

$NPV = \Sigma\, PV(t) = \Sigma\, FV(t)/(1+R)^t = \Sigma\, CF(t) / (1 + R)^t$ with t between 0 and T

<u>Example:</u> An investment of 10 Mio Euro, with cost of capital (= interest rate = weighted expectations of return of the owners and debtors) of 10%, turns out 3 Mio Euro in the 1st year, 5 Mio Euro in the 2nd year and 7 Mio Euro in the 3rd year. Would you invest?

Present value of the project: $(-10 + 3/1{,}1 + 5/(1{,}1)^2 + 7/(1{,}1)^3)$ Mio €
$= (-10 + 2{,}73 + 4{,}13 + 5{,}26)$ Mio €
$= 2{,}12$ Mio €

Thus, the project creates value exceeding the cost of capital and should be accepted.

Why is the NPV-Rule a Good Basis for Investment Decisions?

Characteristics of the NPV-rule:

- Measure of value creation (NPV> 0 : value is generated)
- Time-adjusted
- Risk-adjusted
- Additive (several projects can be viewed together)

Cash-Flow Based Valuation

NPV: Net present value

- calculates the value of a future project today

NPV= $SumC_t/(1+r)^t$
with t from 1 to T
r: weighted average cost of capital
C: cash in- or out-flow

Investment rule: **Invest, if NPV greater or equal than 0**

IRR: Internal rate of return

- calculates the discount rate of a stream of future cash flows

IRR = iteratively calculated from NPV formula, with NPV=0, r=IRR

Investment rule: Invest, if IRR greater or equal than your cost of capital (or greater than similar other investment opportunities)

IRR and NPV will not always lead to the same decision

Both methods do not capture the managerial flexibility (to defer, alter, expand a decision)

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Option Pricing

Advantages

- Option pricing allows to incorporate time value and managerial flexibility (f. ex. to stagger, defer, expand an investment)

Disadvantages

- Often mathematically complex equations

Methods

- Analogous model to financial call options and usage of (modified) **Black-Scholes model**
- **Decision tree** (probabiliticied NPV)
- Intermediate methods (Monte-Carlo Simulation of several variables)

All Option pricing methods use the **risk-free discount rate** (r_f) and incorporate the project risk in the options!

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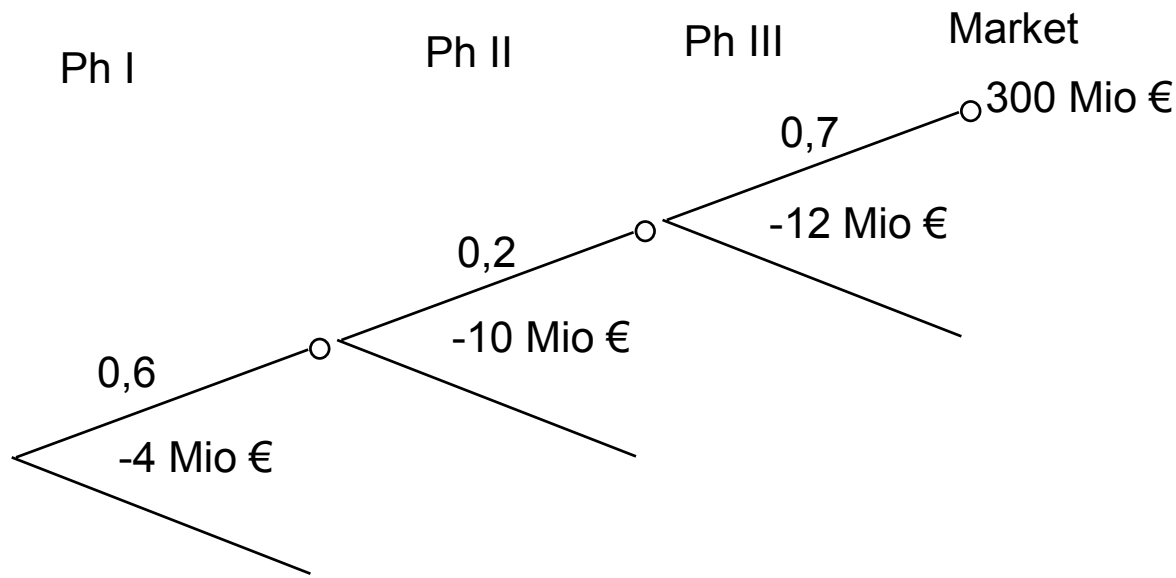
Decision Tree Calculation

Applicable, if decision points are identifiable (analytical results, entrance into clinical studies, discontinuous cash flow)



Year	0	1	2	3	
CF components	-4	0 * 0,4 -10 * 0,6	0 * 0,6 * 0,8 -12 * 0,6 * 0,2	0 * 0,4 * 0,2 * 0,3 300 * 0,6 * 0,2 * 0,7	
CF	-4	-6	-1,44	25,2	
DCF	-4	-5,22	-1,09	16,57	r = 15%

NPV = 6,26 Mio € (for comparison: NPV without decision points: 175,58Mio €)

Value Creating under Consideration of Freedom to Decide

Project	**Cash Flow** (€ in year 1;2;3;4)	**NPV** (€)
no risk	-4;-10;-12;300	175,58
overall risk with 92% P	4;-10;-12;300 (P 0,08)	-6,0
1 decision to exit before phase III (identical overall risk)	4;-10;-12 (P 0,12);300 (P 0,7)	0,03
2 exit decisions (before phase II and phase III / identical overall risk)	4;-10 (P 0,6);-12 (P 0,2);300 (P 0,7)	6,26

All project values lay in between these two extrema

Every additional option (to exit) increase the value of the project

Exit **options generate** a **value** of more than 12 Mio € , compared to the traditional NPV calculations.

Probabilities for risk at clinical trials can be derived from public statistics.

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Real Option Pricing (Black-Scholes Model)

Apply by unknown or uncontrollable decision points (e.g. market development, predominant exogenous risk)

Value of option C = **$S*N(d1)-Ee^{-rt}N(d2)$** (Black & Scholes)
with d1 = $(\ln(S/E)+rt+0{,}5v^2t)/\mathrm{rad}(v^2t)$
and d2 = d1- $\mathrm{rad}(v^2t)$
N(d): probability that a standardised, lognormally distributed random variable will be less than or equal to d

Analogy of call options to investment opportunities:

5 Variables:	**Call options**		**Investment Projects**
E:	exercise price	→	investment to acquire project resp. option
S:	stock price	→	present value of project
r:	risk-free rate of return	→	time value of money
v^2:	variance of return of stock	→	riskiness of project
t:	years to expiration	→	length of possible decision deferral

If t = 0 (no option), C becomes S - E, corresponding to NPV = PV(project) minus Investment

A Simplified Method to Calculate the B.-S. Model

To avoid complex calculations, the C values are tabulated (as percent of the investment) as a function of two new variables, encompassing the 5 known variables:

NPV_q = S/PV(E)= operating value of option/discounted investment for option (contains t, r, E, S)

cumulative volatility = v*rad(t) (contains v and t)

	NPV_q →
v*rad(t) ↓	B.-S. values of option, expressed as percentage of S

To find S and E of the option deduct cash flows without the option and separate operating cash flows (S) from investments (E)

To find standard deviation v:
- -benchmarking:
  - -US stock index: v=20% p.a.
  - -GM stock price: v=25% p.a.
  - -Single projects: v=30 - 60% p.a.
- -Simulations: Monte-Carlo
- -Calculation of similar projects (inverse use of B.-S. Model)

NPV (project) = NPV(without option) + S * table value

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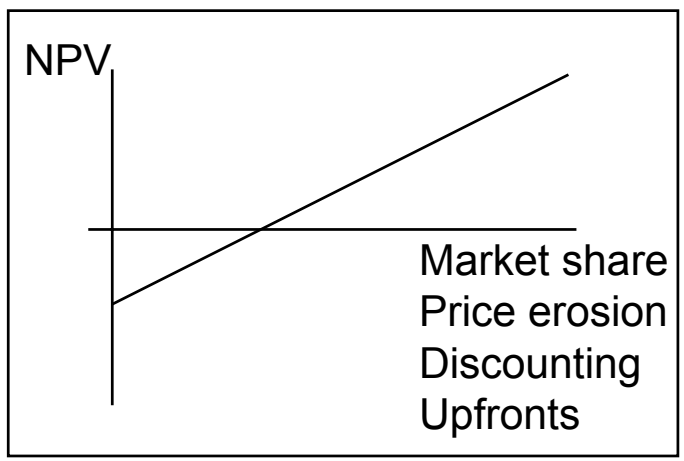
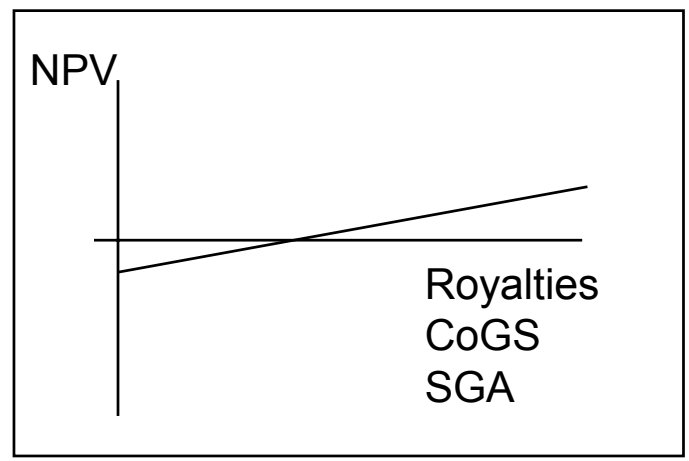
Sensitivity Analysis

! To learn about the importance of project variables, and to estimate the influence of rough estimations (f.ex. risk), always perform a sensitivity analysis. You will also get information on the critical decision points to spend more money on to improve the value of the project.

Generally big influences



Generally small influences



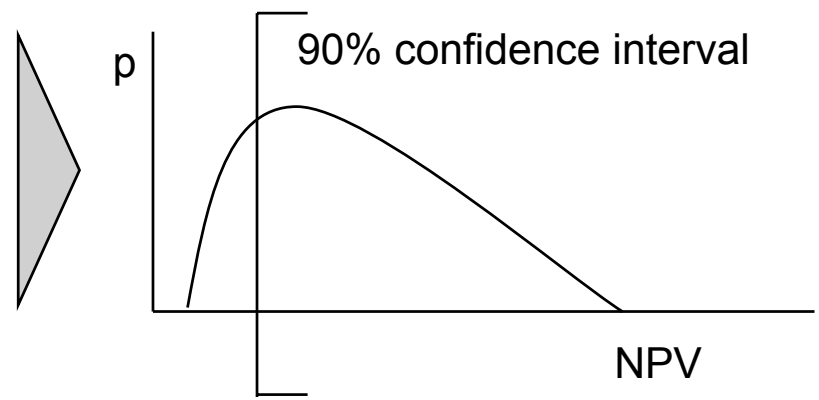
Monte Carlo Simulations of Project Values

Excel-based software that generates thousands of possible outcomes by varying several variables at the time.
The variables are defined by the user (set limits and distribution function)
Outcome is f. ex. an NPV distribution with a probability („with 95% confidence, the NPV will be greater than 0“)

Replaces the scenario analysis and saves time to evaluate many different possibilities. Good understanding of project is required.

Software programs are available (Crystal ball, @Risk)

Set variables:
-Market share: 5-10%, normal log
-Development cost: 20 - 40$, triangular
- Production cost: 10 - 15%, binominal



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Helps for Valuating a License Agreement

Introduction:

Valuation methodology:

- Cost plus margin: Do not use: buyer purchase a value, not the costs of the seller!
- Comparisons: difficult to obtain, not very advantageous
- Discounted cash-flow models (NPV): additionally, include the flexibility and market variance!

Statistics

Point of time of the deal	Discovery	Preclinics	Phase I/II	Phase III	Approval/ Registration
Years to market	12 - 8	10 - 7	8 - 5	6 - 2	2 - 1
Upfronts ($Mio)	1 - 20	1 - 30	2 - 40	5 - 50	20 - 60
Royalty (%)	2 - 8	2 - 10	2 - 12	8 - 16	8 - 20

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Market Estimations - Sources

Websites:
decisionsstrategies.com
real-options.com
realoptions-software.com
decisionengineering
royalty source.com
recap.com
autm.net
hoovers.com
phrma.org
reutershealth.com and more

Datatools:
IMS (life cycle, R&D focus, Medibase, Pharmacast&beyond, Dataview-MIDAS)
GPI
Lauer Taxe/Rote Liste
Pharmasearch
Pharmadynamics

Primary research:
IMS consulting
Dun and Breadstreet
Hirsch & Gayer

Market reports:
Datamonitor
Decision recources
analyst reports
company informations

General info-tools:
Medical World review
Statistisches Jahrbuch
Scrips
Medical literature

Data as independent as possible, including raw data

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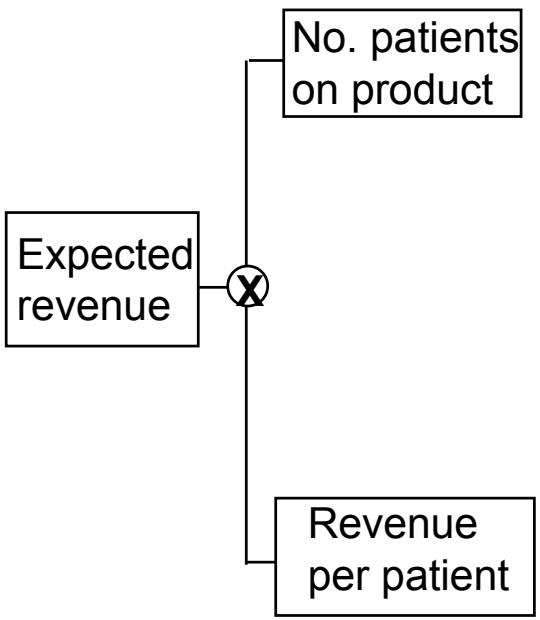
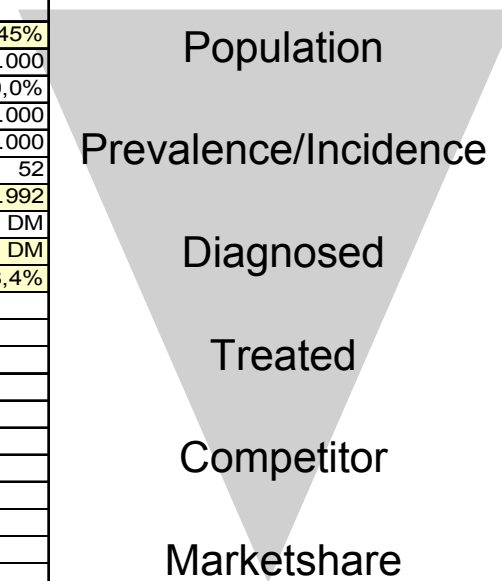
Example of Market Size Evaluation (bottom-up)

Patient flow analysis



		2000	
		Deutschland	Frankreich
	Bevölkerung	82.000.000	58.000.000
Indikation	**Nierenerkrankungen**		
	% Dialyse	0,059%	0,045%
	# Dialyse	48.000	26.000
	% Therapiert	85,0%	60,0%
	# Therapiert	40.800	12.000
	Dosierung/Woche	8.000	8.000
	Therapiewochen/Jahr	52	52
	Units (Mio.)	16.973	4.992
	Preis/1000 Units	22,00 DM	18,00 DM
	Umsatz (Mio.)	373 DM	90 DM
	% vom Gesamtumsatz	94,9%	78,4%
	% Predialyse		
	# Predialyse		
	% Therapiert		
	# Therapiert		
	Dosierung/Woche		
	Therapiewochen/Jahr		
	Units (Mio.)		
	Preis/1000 Unit		
	Umsatz (Mio.)		
	% vom Gesamtumsatz		
	Krebsleiden		
	# Relevante Krebsleiden		700.000
	% Chemotherapie (Cisp)	0,04268%	0,03966%
	# Chemotherapie(Cisp)	35.000	23.000
	% Therapiert m. Epo	5,0%	13,0%
	# Therapiert m. Epo	1.750	3.000
	Dosierung/Woche	45.000	45.000
	Therapiewochen/Jahr	10	10
	Units (Mio.)	788	1.350
	Preis/1000 Unit	22,00 DM	18,00 DM
	Umsatz (Mio.)	17,33 DM	24,30 DM
	% vom Gesamtumsatz	4,4%	21,2%
	Summe Patienten	**42.550**	**15.000**
	Summe Units (Mio)	**17.887**	**6.368**
	Effektiver Preis	**22,00 DM**	**18,00 DM**
	Rabatt	10,20%	18,18%
	Mittlerer HA-Preis	24,50 DM	22,00 DM
	Summe Umsatz	**394 DM**	**115 DM**



Compared to financial analyst reports (Dt. Bank, Frost and Sullivan, SG Cowen)- **Top down**

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Modelling the Future

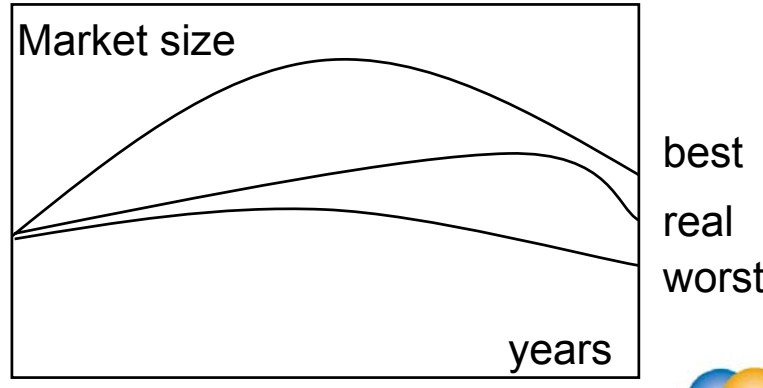
Externalities:

Competition
Substitutions
Legal/environmental
payor

Assumptions (Scenarios)

Market share Substitutes
Pricing level Substitutes (Premium?)
Market price drug/price erosion (30 - 51%)
Number competitors (4 - 8)
Growth rate patients (0 - 8%)
Patent-free countries/generic percentage
Own market share EU (5 - 10%)
Own pricing level (-11 - -15%)
CoGS (15 - 20% of sales)
SGA (5 Mio DM + 15% of sales)

3 different scenarios, modelling the best, real and worst case



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Simple NPV Calculation

Year	2000	2006	2007	2008	2009	2010
EU sales	1334	1504	1579,2	1658,16	1741,068	1828,121
growth rate		5%	5%	5%	5%	5%
pricing		25%	30%	35%	40%	44%
Substitutes		10%	10%	12%	13%	14%
EU sales corrected	1334	1015	995	948	909	880
accessible (entrance barri	0	89,02%	89,02%	94,91%	100%	1
Total market		904	886	900	909	880
own price erosion			14%	13%	10%	8%
own market share			0,03	0,05	0,06	0,07
own sales		**0**	**23**	**39**	**49**	**57**
Royalties/COGS		-13	-7,50	-7,50	-7,50	-7,50
Royalties 10-20			-3,00	-3,00	-3,00	-3,00
Royalties 20-30			-2,00	-2,00	-2,00	-2,00
Royalties >30				-0,62	-2,11	-3,25
Development						
SGA		0	-5	-8	-10	-11
Sublicense		0				
Sum	0	-13	6	18	25	
NPV	20,22 DM					

Modelling of a „reasonable“ sales curve (life cycle)

All calculations take 10 years sales into account, no „terminal value“

NPV with 15% discount rate

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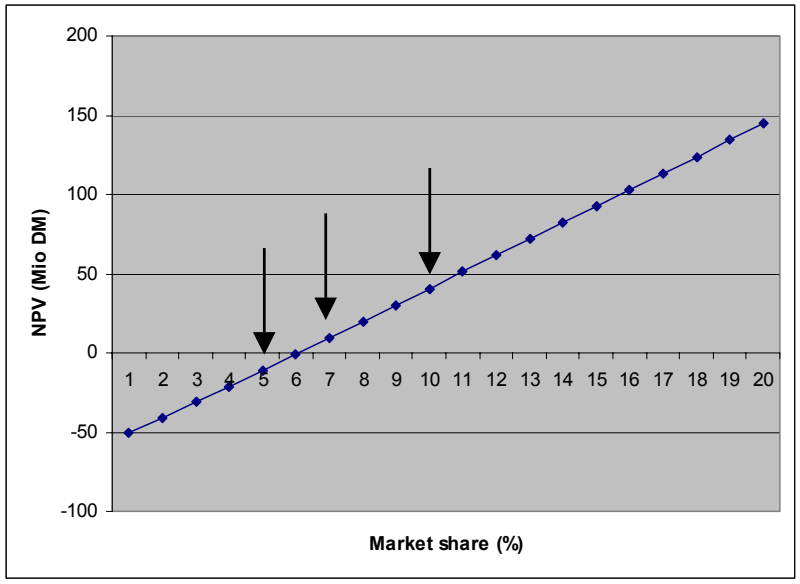
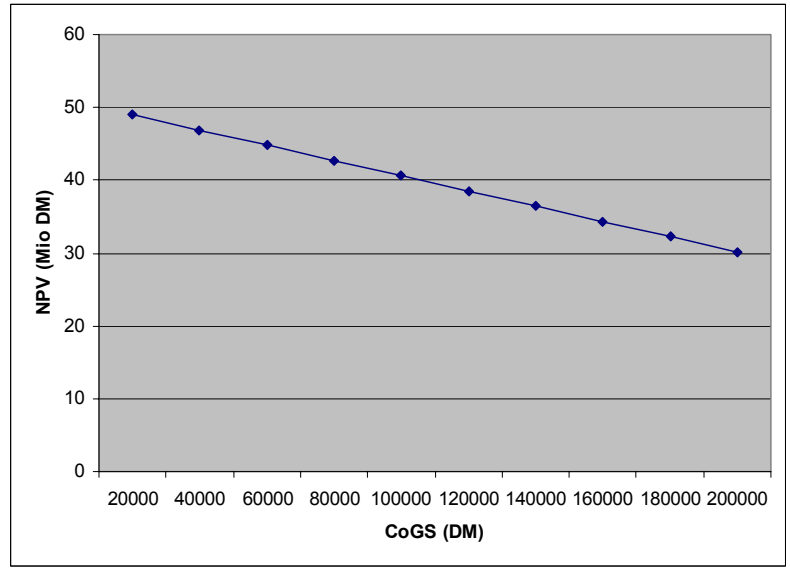
Sensitivity Analysis

The NPV is influenced more by the market share than by the CoGS, break-even point of NPV is at 6,2% market share, worst case scenario 5%, real 7%, best 10%.





Option to Stop the Project Before Clinical Studies

General benchmarks for success rates of novel developments (IMS)
Phase I: 62%
Phase II: 44%
Phase III: 73%
Registration: 91%

18% of the development projects enter the market (differs among different TAs)

No decision tree:

$NPV_{project}$ (0,15):12,60 Mio DM

$NPV_{preclinics}$ (0,15): -26,16 Mio DM

$NPV_{clinics}$(0,15): 38,76 Mio DM

$NPV_{preclinics}$ (0,055): -30,16 Mio DM

$NPV_{clinics}$(0,055): 116,55 Mio DM

With decision tree:

NPV(p, 0,055):

Go:60% — 86,39 Mio DM

No-go:40% — -30,16 Mio DM

$NPV_{project}$: 39,77 Mio DM

Option to abandon the project creates 27,17 Mio DM additional value

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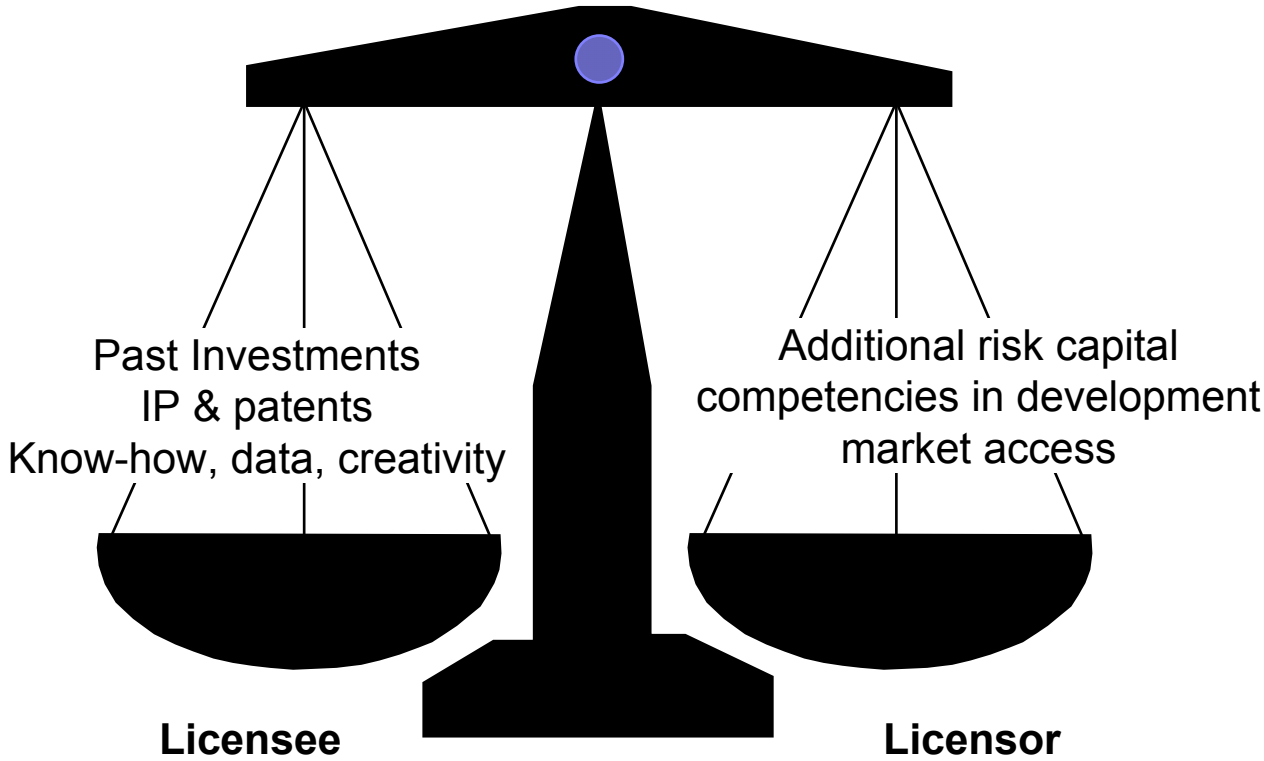
AGENDA

- Deal making: the economic backbone of companies
- An introduction to valuation and the theory of net present value calculation
- Advanced methods of valuation
- Practical considerations: numbers, sources and markets
- **Case studies: How to divide the value**
- Conclusion

How to Divide the Value of the Project?

The value of the project - after deduction of all costs - shall be fairly allocated to allow a **win-win partnership** and keep both parties alive and motivated. The merits and contributions of each partner can be arguments in the negotiations, if purely financial reasons are not strong enough.



Source: adopted from Dr. U. Koch

Case study: Pros and Cons of a cooperation between two Biotech`s

Example: Co-operation on 50/50 cost split

	Pro	Con	Conclusion
Early development	Securing of best option	Loss of a time advantage	Time advantage can be at risk
AIP production	Easier access to valuable manufacturer	Loss of flexibility	If bottle neck exists, accept loss of flexibility
F & F	Bargain power	Loss of flexibility	see above
Clinical studies and regulatory approval	Cost cutting	Loss of a strategic advantage	Cost cutting more important
Patent know-how	Highest safety	Loss of a strategic advantage	Joint strength allow effective litigation
Distribution	Better off-warding against other competitors	Simultaneous launch of 2 identical products	Only disadvantage if one partner has high chance to be first on the market

Source: BGX

Case study: Valuation of the co-operation - viewed by partner 1

Cost factor	Financial impact	Probability of realisation	Resulting financial component
Dividing in half of the development costs	35 Mio €	90%	31,5 Mio €
Abandonment of a time-to-market advantage	6 months * 1,4 Mio € = 8,4 Mio €, + market share (2% p.a.), 12 Mio € p.a. for 2 years	70%	(22,7 Mio €)
Repeated tech-transfer	2 Mio €	80%	1,6 Mio €
Loss of flexibility	2 months * 1,4 Mio € = 2,8 Mio €	50%	(1,4 Mio €)
Cost saving production	ca. 10%, ca. 1,2 Mio € p.a. , 10 years	70%	8,4 Mio €
Resulting NPV-component			**14,52 Mio €**

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Case-study: Valuation of a co-operation - viewed by partner 2

Cost factor	Financial impact	Probability of realisation	Resulting financial component
Dividing in half of the development costs	35 Mio €	90%	31,5 Mio €
Transfer of research results	15 Mio €	100%	15 Mio €
Usage of established infrastructure (free of charge)	2 Mio € p.a. = 10 Mio €	100%	10 Mio €
Gain of time-to-market	6 months * 1,4 Mio € = 8,4 Mio €, + market share (2% p.a.), 12 Mio € p.a. for 2 years	70%	22,7 Mio €
Loss of flexibility	2 months * 1,4 Mio € = 2,8 Mio €	50%	(1,4 Mio €)
Cost savings production	ca. 10%, ca. 1,2 Mio € p.a. , 10 years	70%	8,4 Mio €
Resulting NPV-component			**58,34 Mio €**

Case-study: Conclusion

A co-operation is, in the view of partner 2, financially more rewarding than an own development. Partner 2 would profit much more than partner 1 and could develop the product cheaper than partner 1.

Therefore, the financial terms need to adjust this imbalance by asking for a NPV-component payment of **21,9 Mio €** (=(58,3 Mio €-14,5 Mio €)/2).

This can be achieved by

- a 15 Mio € upfront (purchase of research result) plus a payment of 3 Mio € p.a. during the development (02-05) for use of infrastructure

- or by a smaller upfront and a small amount of royalties, depending on the projected sales.

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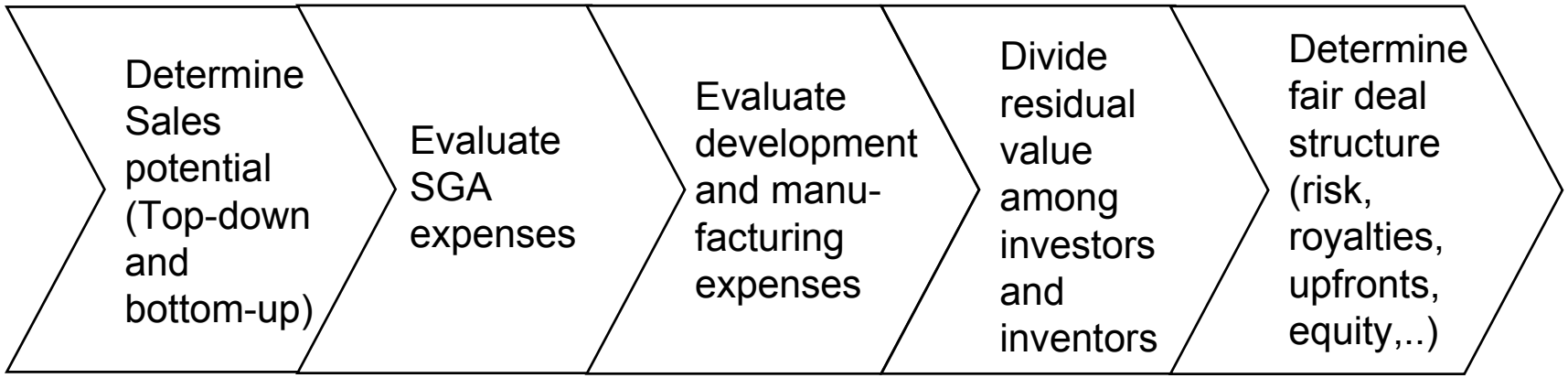
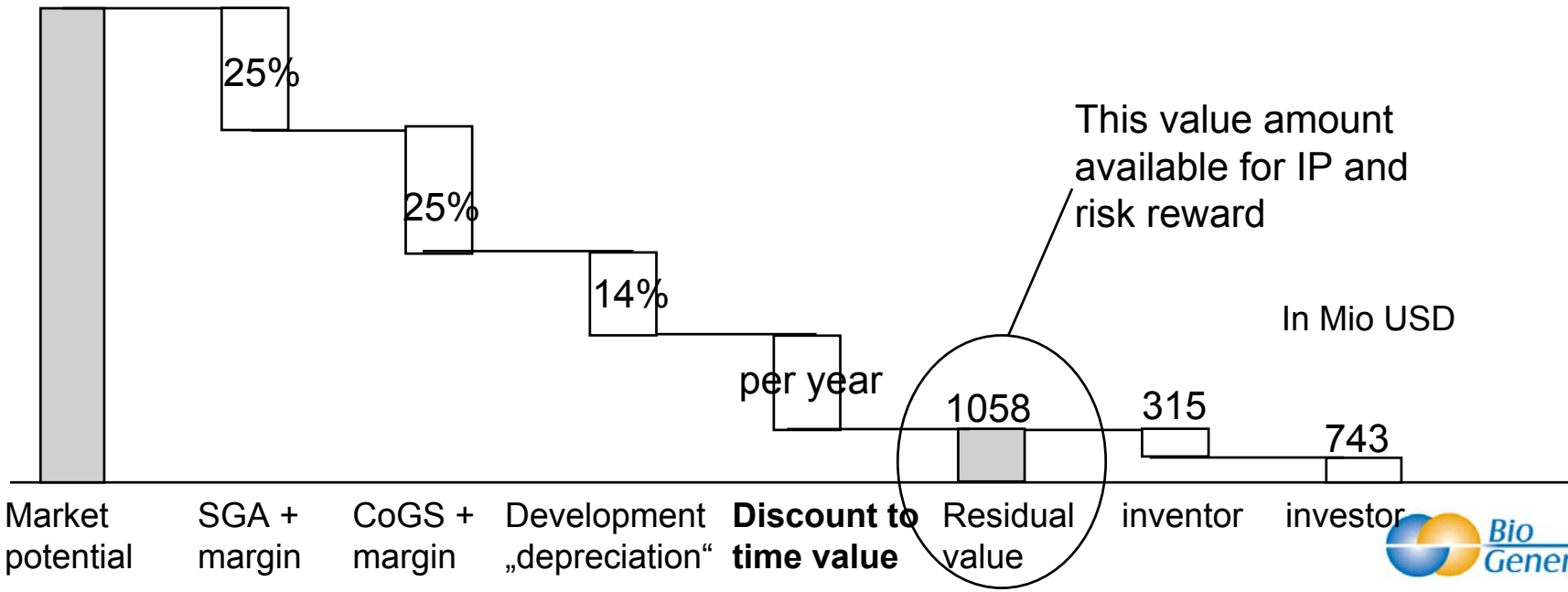
Case Example: Biochem Pharma - Glaxo Deal: Re-Valuation





Case Example: Biochem Pharma - Glaxo Deal: Re-Valuation

The financial consequences of the deal between Biochem Pharma and Glaxo:

The Break-even at Biochem Pharma was reached in 1995.

In 1998, Biochem Pharma received 107 Mio USD (13%) from total sales of 824 Mio USD. The market capitalization (at this time) exceeded 3 Bil. USD

This was a successful deal for both companies.

However, the biotech company should have, *mathematically speaking and in retrospective,* asked for 26,7 % royalties instead of 13%, when considering the income streams, risks and investments, to make it a fair deal.

Clearly, other compounds also play an important role in the outcome.

Source: Moscho et al: Nature Biotech

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Conclusion: Valuation and its limits

- Financial deal-making follows company strategy
- Financial framework helps managers to define the acceptable limits
- The financial model deals with overall values, not costs
- All financial models are „perfect market“ models, with free offer and demand and equal information level on both sides. This is almost never the case in the pharmaceutical industry, theories are not completely suitable
- The deal structure also includes the strength and contributions of the partners, risk taking and indemnifications/guarantees; ownerships
- Always consider other (external) factors: Market growth, substitutes, rivals, payors, legal issues...

•Therefore: **Financial models are arguably the most important prerequisite for licensing deals, but they are not the only truth.**

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