

A close-up, high-resolution photograph of a person's face, focusing on the eyes and nose. The person has light-colored eyes and is looking directly at the camera. The image is slightly blurred, giving it a soft, artistic feel.

THE VALUATION EXPERTS

**Innovative Business Solutions and
Smart Financing: Focus on Valuation**

Dr. Patrik Frei

October 2016 | Vienna, Fit for Health 2.0

Overview

Valuation and Negotiation in Life Sciences

Part 1:

- **Financing Sources**
- **Company Valuation**

Coffee break (10.30 – 11.00)

Part 2:

- **Product Valuation**
- **Case Study**

Venture Valuation

Mission

Independent assessment and valuation of technology driven companies / products in growth industries

**Life Sciences Database Biotechgate.com
With Company profiles, licensing opportunities, investors and licensing deal information**

- Experts Finance / Biotech-Pharma
- Not a venture capitalist
- International experience (Asia, Europe, North America)
- Track record of over 400 valued companies
- Clients such as NVF, Fraunhofer Gesellschaft, European Investment Bank; VCs; Arpida/Evolva

Funding gap

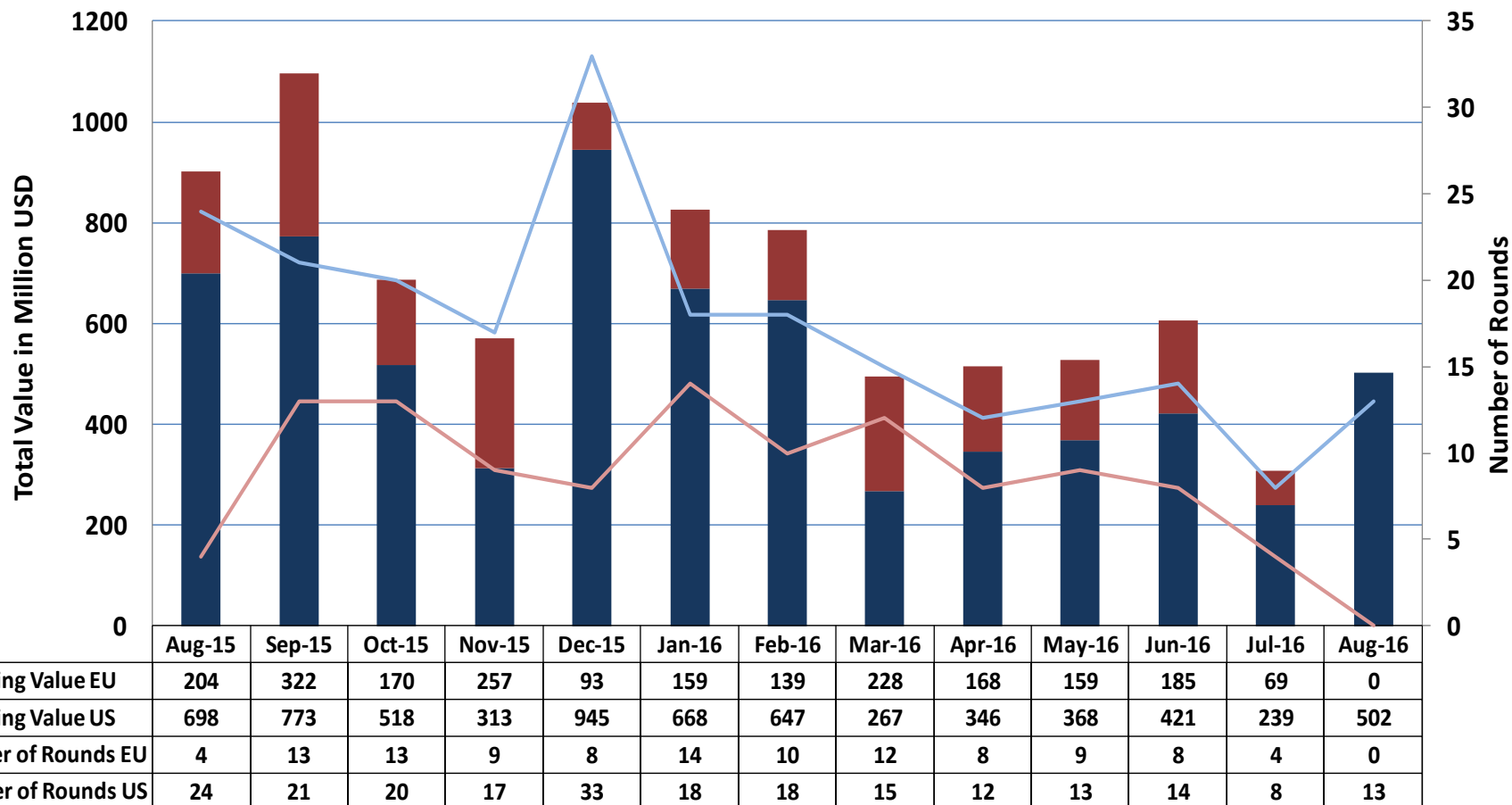
- Increasing cost of development
- Higher hurdles for registration
- Disappointment of investors
- General risk adversity of market



=> Less capital available for earlier stage companies

Biotech Financing

Biotech Therapeutic Financing Rounds



Source: Biotechgate.com

Financing Trends



How do companies cope with lack of VC money?

- Corporate Investors becoming more important
- Licensing as key source of funding
- Fee for Service as a way of financing innovation
- Product / Project financing by VCs
- Public money is very important

Financing Sources

1. **Own development => resources needed**
 - Own financing (Services)
 - Public: Grants / Government Funding
 - a) Regional
 - b) National
 - c) European / international
 - Raise capital
 - a) Equity (VC, Corporate, Family Office, BA)
 - b) Venture Debt / Convertibles
 - c) Product Financing
2. **Out-licensing**
 - Value retention; lead vs. follow-on products

Equity Finance

	Venture Capital	Corporate Investors	Family Offices	Business Angels
Size	> USD 5 m	Open	Open	< USD 2m
Company type	High risk / potential	Strategic fit, innovative	Service component, opportunistic	Seed / early stage
Total capital requirement	High	High	Medium	Low
Exit	Set 5-10 years	M&A	Long-term partner	Medium term

Non-Equity Finance

	Public Grants / Government	Private Grants	Convertibles	Revenue, Royalty Product Financing
Size	< USD 2 m	< USD 5 m	open	> USD 10 m
Company type	Innovative, R&D, early stage	Innovative, R&D, niche markets,	High growth, later stage	Mature, later stage
Total capital requirement	All	All	All	High
Exit	None	None	Repay / convert	none

Don'ts in VC preparation

- Don't use highly technical descriptions of products
- Don't make vague or unsubstantiated statements
- Don't ignore or underplay your competition
- Don't ignore key risks
- Don't take the funding process lightly
- Don't try to raise between significant milestones
- Don't be afraid to ask for adequate funding

Dos for VC preparation

- You need a Business plan
- Be specific. Substantiate statements with market data
- Summarize and properly structure financial information;
- Show how much money you need; how do you spend it
- Network like crazy
- Do reference checks on the VC (previous investments)

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Part 1:

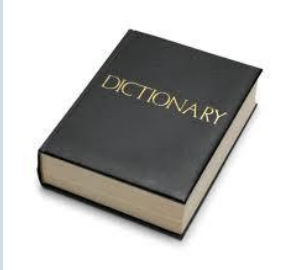
- **Financing Sources**
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Coffee break (10.30 – 11.00)

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Why Valuation?



- **Value:** implies the inherent worth of a specific thing
- **Price:** depending on the market (supply / demand); whatever somebody is prepared to pay

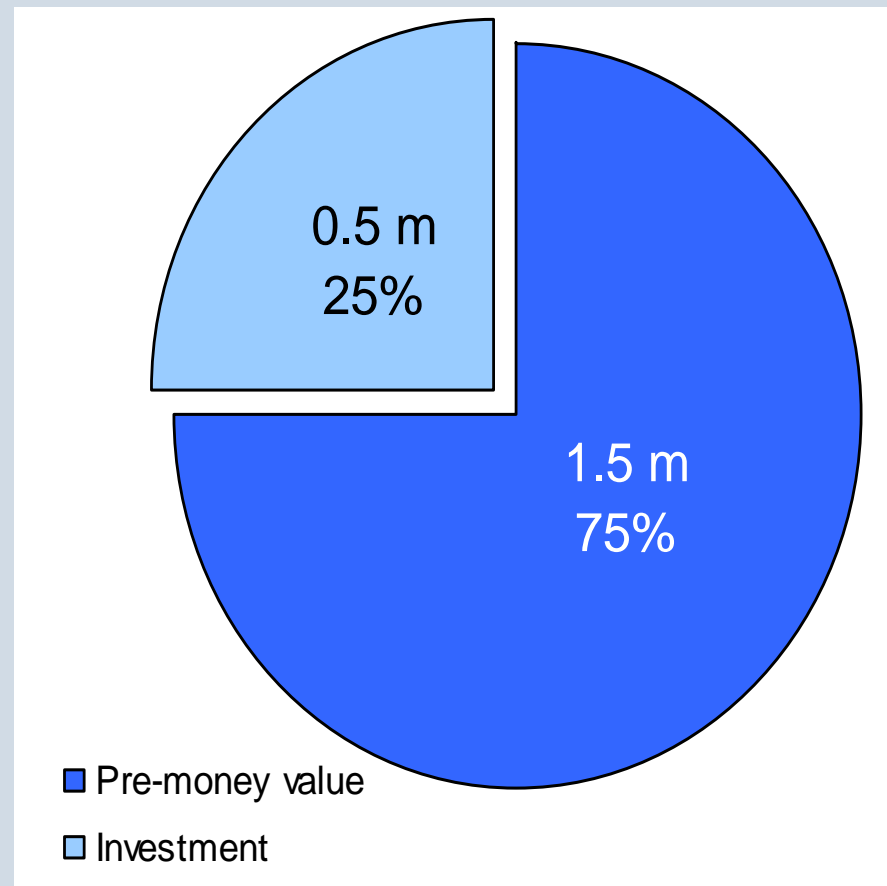
“Price is what you pay. Value is what you get.”

By Warren Buffett

=> Provide basis for negotiation, investment decision, fair share price

Why Valuation

- Value before investment (pre - money value): EUR 1,5 m
- Investment: EUR 0,5 m
- Value after investment (post-money value): EUR 2,0 m
- Share Investor:
 $0,5 \text{ m} / 2 \text{ m} = 25\%$



Why Valuation

- Out-licensing of a phase II product
- Deal terms:

up-front	CHF	1 m
milestones	CHF	20 m
royalties		7%
- rNPV of product ?
- rNPV of deal ?

- ⇒ rNPV of product: CHF 30 m
- ⇒ rNPV of deal: CHF 10 m
- ⇒ Split Biotech / Pharma: 33% / 66%

rNPV: risk adjusted net present value

Biotech Valuation



- Valuation is key issue in development
- Industry lacks transparency (private)
- Very difficult (high uncertainties)
- High potential for investors
- Long investment cycle
- Traditional valuation methods unsuited
- Complex technology and IP situations

Mind-set of Investors



- Take high risk, but expect high returns
- Pressure from investors
- Compete in capital market

	Probability of failure	Return
Government Bond	0%	3%
Bonds	5%	5%
Blue Chip Company	10%	9%
Internet company (Nasdaq)	50%	20%
Biotechnology Company	80%	50%

Risk as a major factor



1. How can we capture risk?
=> Assessment of the company
2. How can risk be quantified?
=> rating of factors

Assessment



1. Understand the fundamentals
 2. Assumptions drive the valuation
- ⇒ Assessment/assumptions are key

Assessment

Company

Product

1. Management



2. Market



3. Technology



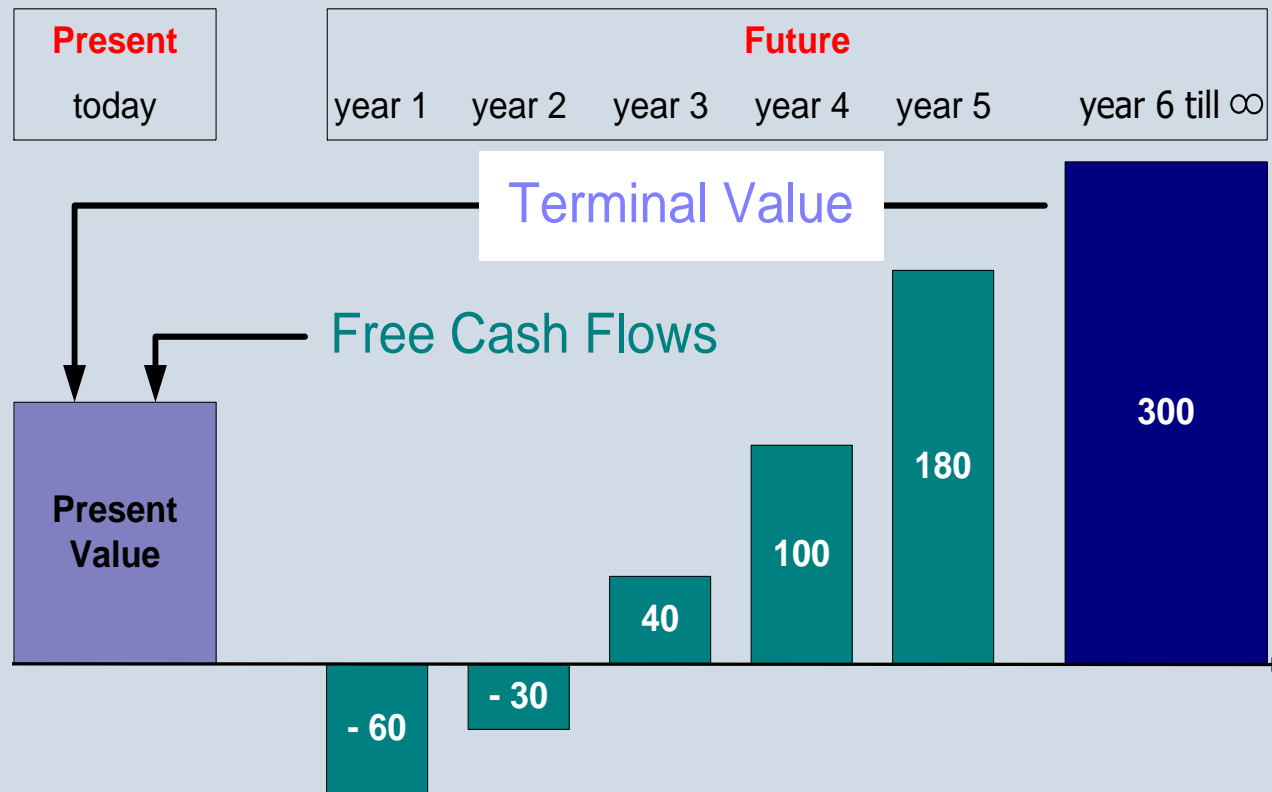
Valuation Approaches

- Operations-based methods:
 - ⇒ *business plan, fundamentals*
 - Market-based methods:
 - ⇒ *price, trends, comparison difficulties*
-
- | | | |
|-------------------------------|---|--------------------|
| – Discounted Cash Flows (DCF) | } | Operations methods |
| – rNPV | | |
| – Real Options | | |
| – Venture Capital method | ⇒ | Mixed method |
| – Market Comparables | } | Market methods |
| – Comparable Transactions | | |

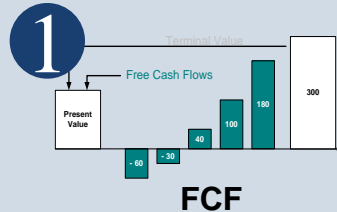
⇒ there is no “the right method”

⇒ combination of different methods

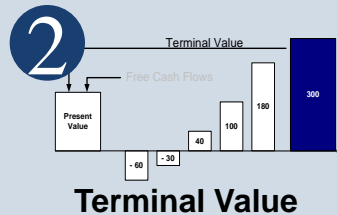
Basic DCF



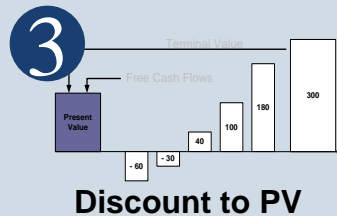
Discounted Cash Flow



Determine Free Cash Flows to year 5 or y3 / y10



Calculate Terminal Value



Discount with Discount Rate



Sum of Discounted Free Cash Flows

Discount rate

Assumptions: interest rate $i=10\%$

today (K_0)

future (K_1) (n=5 years)

1.00 EUR

1.61 EUR

$$K_0(1+i)^n$$

0.62 EUR

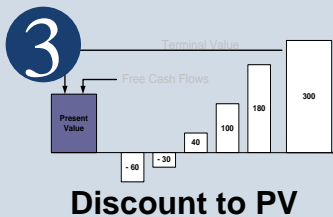
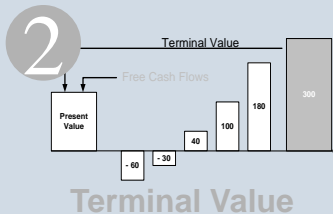
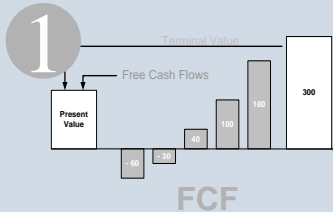
1.00 EUR

$$K_1/(1+i)^n$$

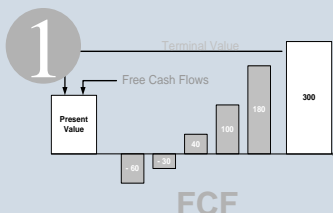
Content of the discount-rate:

- Depreciation of currency and
- Risk => Qualitative analyzes

=> = 1.6 X



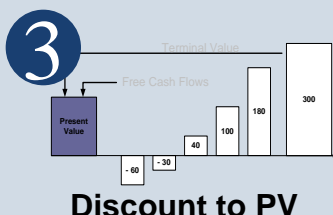
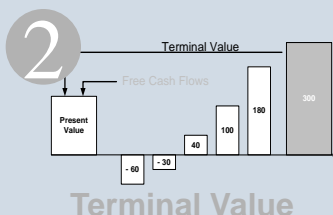
Discount rate



a) Company stage

1 Seed Stage	leads	70% to 90% (20x)*
2 Start-up Stage	pre-clinical	50% to 70% (10x)*
3 First Stage	phase I	40% to 60% (8x)*
4 Second Stage	phase II	35% to 50% (6x)*
5 Later Stage	phase III	30% to 40% (5x)*

*X-times the investment in 5 years necessary $\Rightarrow (1+80\%)^5 = 19x$



b) Rating based

\Rightarrow Determine area within range

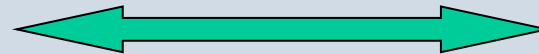
Comparable Methods

**For most Biotechs you cannot use:
P/E, EV/EBITDA, EV/EBIT, EV/Sales**



Company Value:
USD 50 m
50 employees

Ratio



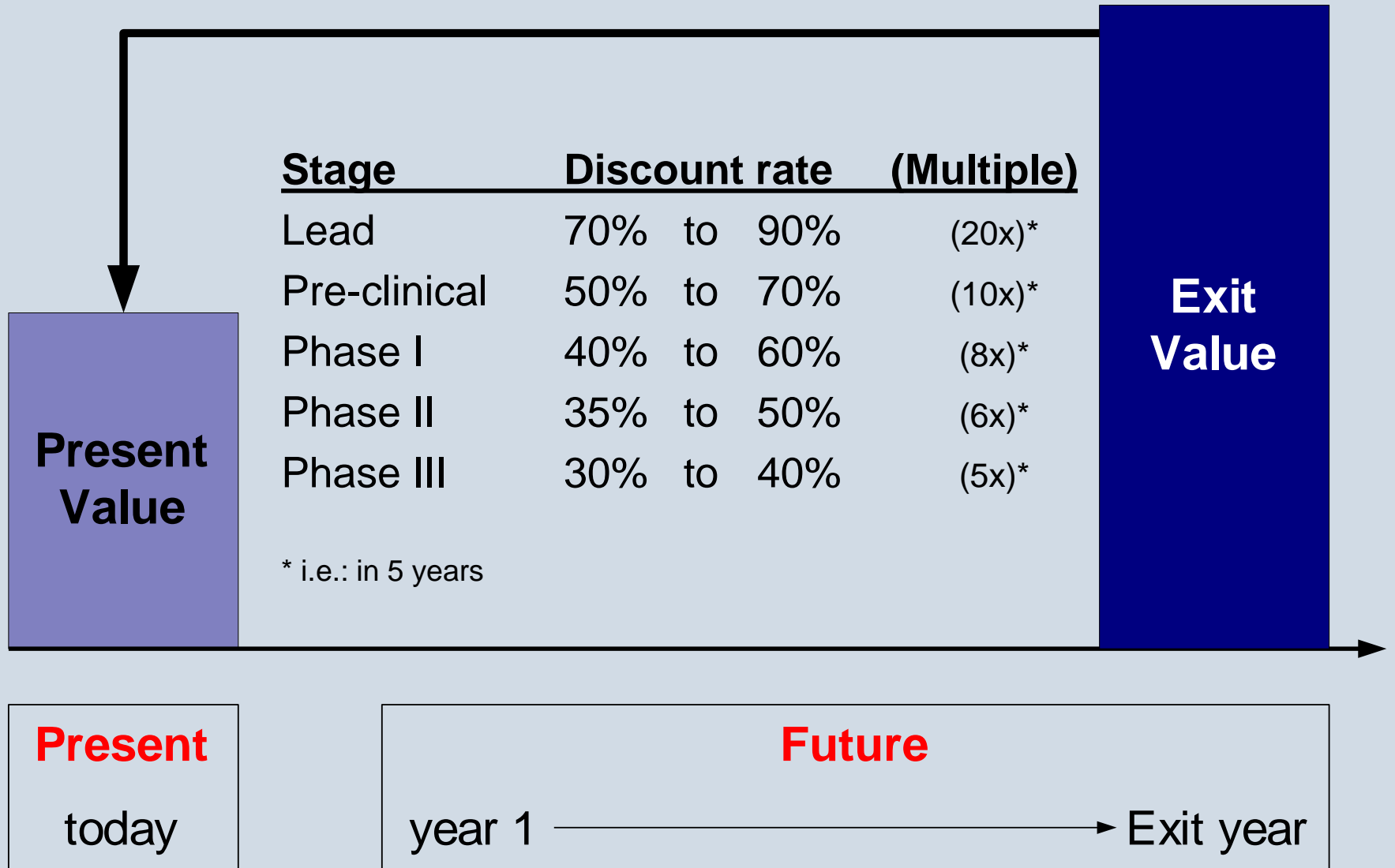
- R&D expenditure
- Employees
- Money raised
- Product in development (p I, p II, p III)



10 employees
⇒ Company Value:
USD 10 m*

* $(50/50) \times 10 \text{ m} = 10 \text{ m}$

Venture Capital Method



Example Glycart



- Glycart acquired by Roche
- For USD 180 m
- Swiss company; founded in 2000 spin-off from ETH in Zurich
- Technology platform to enhance the activity of therapeutic antibodies (cancer / autoimmune diseases)
- Pre-clinical products
- Existing collaboration with Roche (1 year)
- 30 employees

Example Glycart



- Raise USD 31 m in the past
 - Planned to raise another USD 35 m => valuation too low
 - Acquisition offer by mid-sized Pharma
- ⇒ auction process / parallel fund raising

Example Glycart



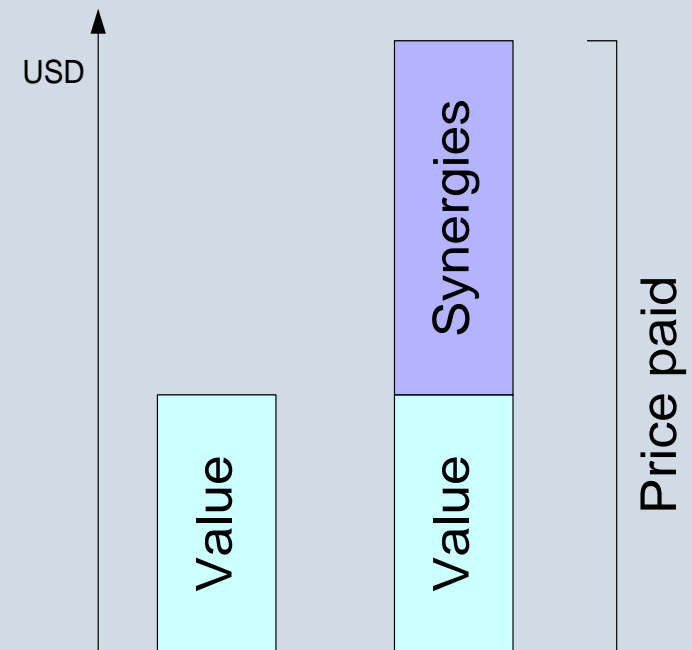
Valuation:

⇒ Pre-clinical compounds USD 180 m?

⇒ Technology Platform?

⇒ Keeping control?

⇒ Value enhancement
for own products?



Conclusion



- Think outside the box / be creative
- Use grants and non-dilutive
... but keep focus
- Valuation is all about the assumptions
- Price vs. Value
- Network, network, network....

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- 2. rNPV product valuation**
- 3. Company valuation**
- 4. Deal structure**
- 5. Case study**

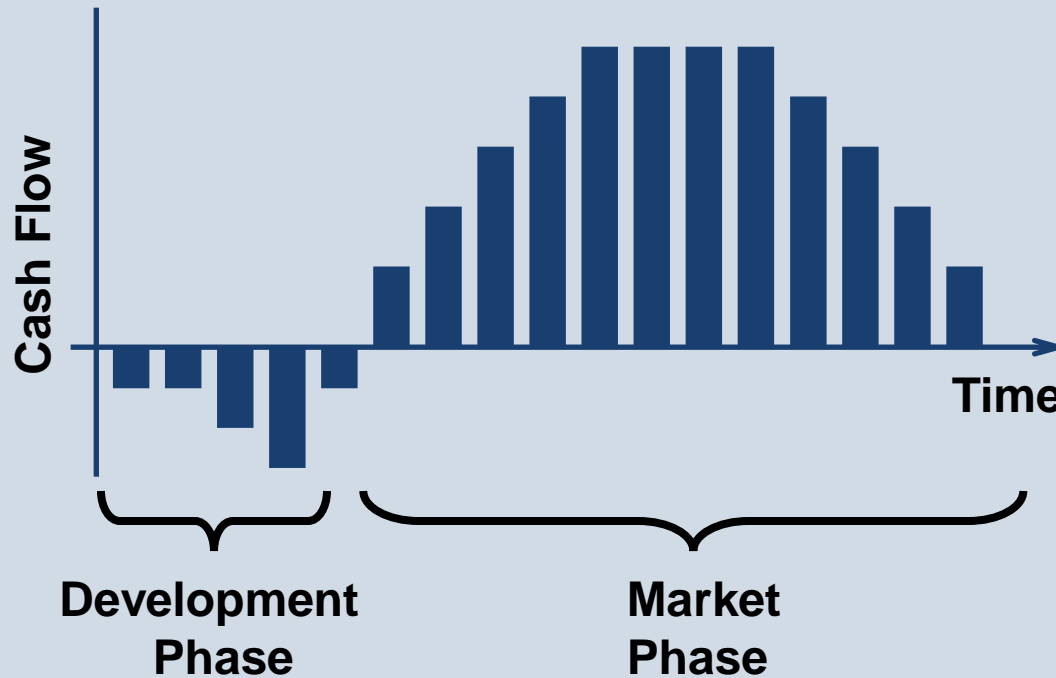
Product Valuation

Valuation of a product

- Licensing deal
- Strategic development decision
- Expenses included are only those relevant to the product
- Management risks not taken into account



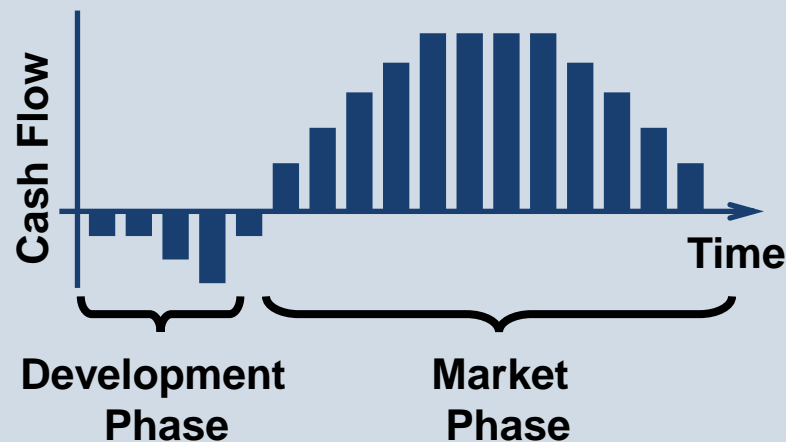
Valuation components



- Determine timelines and cash flows in each phase
- Develop solid assumptions for all key variables

rNPV Valuation

1. Development phase => investment
Product Risk (r) => success rate
2. Market phase => revenues
Patent expiry => end of revenues
(often no terminal value)
3. Discount => non-specific risk (General Risk)



Risk-adjusted NPV

$$\sum_{i=1}^T \rho_i \sum_{t=1}^T \frac{DCF_{it}}{(1+r_d)^t} + \rho_7 \sum_{j=1}^5 q_j \sum_{t=1}^T \frac{CCF_{jt}}{(1+r_c)^t}$$

Risk adjusted Net Present Value

- Also called eNPV
- Method of choice for Big Pharma

Benefits:

- Helps understand accurate value and maximises deal options
 - Adjusts value for **Development Risk** and **Discount rate**
- ⇒ Risk is split in two components
- 1) Product Risk (attrition rate)
 - 2) General Risk (discount rate)

1. Overview of product valuation
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Five Step Process



Determine Cash Flows in **Development** Phase



Determine Cash Flows in **Market** Phase



Discount with **Discount rate**

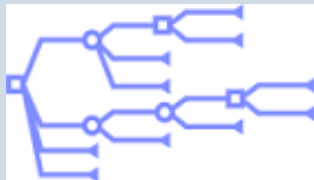


Adjust for **Risk**



Sum discounted risk-adjusted cash flows

rNPV – Example

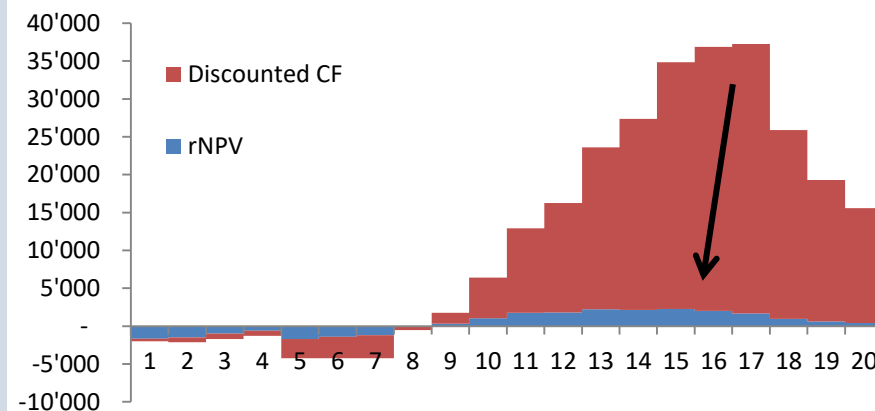
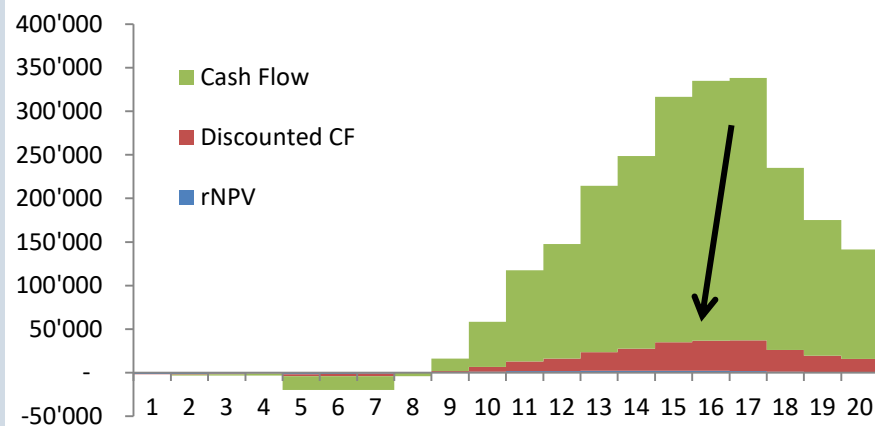


- Phase 1 product
- 20% discount rate
- 11% Probability of success (p1 to market)

⇒ CF: USD 2'269m

⇒ DCF: USD 127m

⇒ rNPV: USD 8m



Development Phase



- Determine cost and duration of clinical trials

- Geographic location
- Number of patients and centres
- Type of treatment



- Manufacturing
- Regulatory affairs
- Long term animal tox. studies
- Misc. administration



Example Trial Inputs



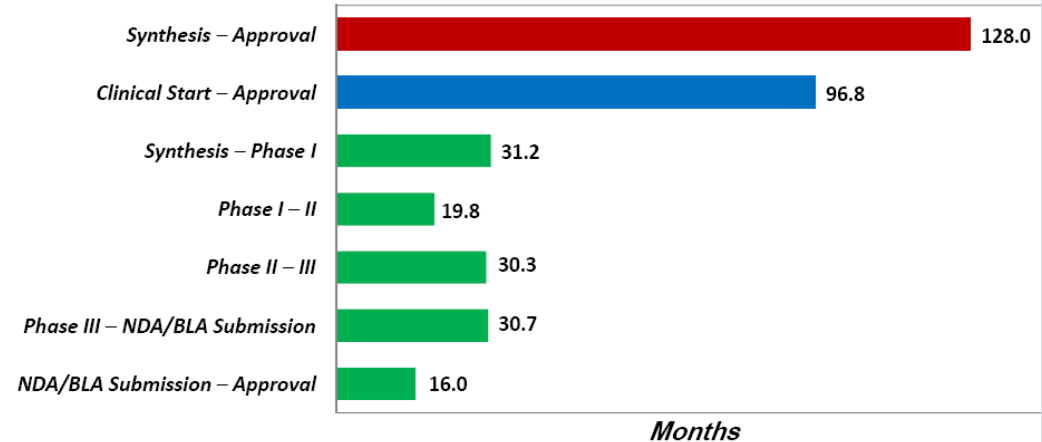
In US\$ 000's	Phase I	Phase II	Phase III	Approval
Time (Years)	1	2	3	1
Number of Patients	~10	~200	~3000	
Cost per patient	7	7	7	
Total Patient costs	70	1400	21000	
Total patient costs as percentage of total costs*	30%	30%	30%	
Total non-patient costs	163	3267	49000	
Total costs	233	4667	70000	2500
Total Development Costs (unadjusted)				77400

* To factor in other cost including animal studies, manufacturing, administration etc.

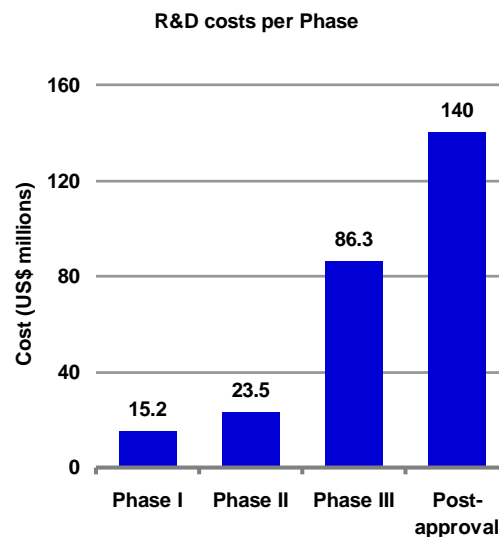
Cost and Lead Times



Representative Development and Regulatory Review Time Profile (synthesis to approval)



Source: Tufts Center, 2014



Source: Business Insights

Market Phase



Develop assumptions to predict the future market



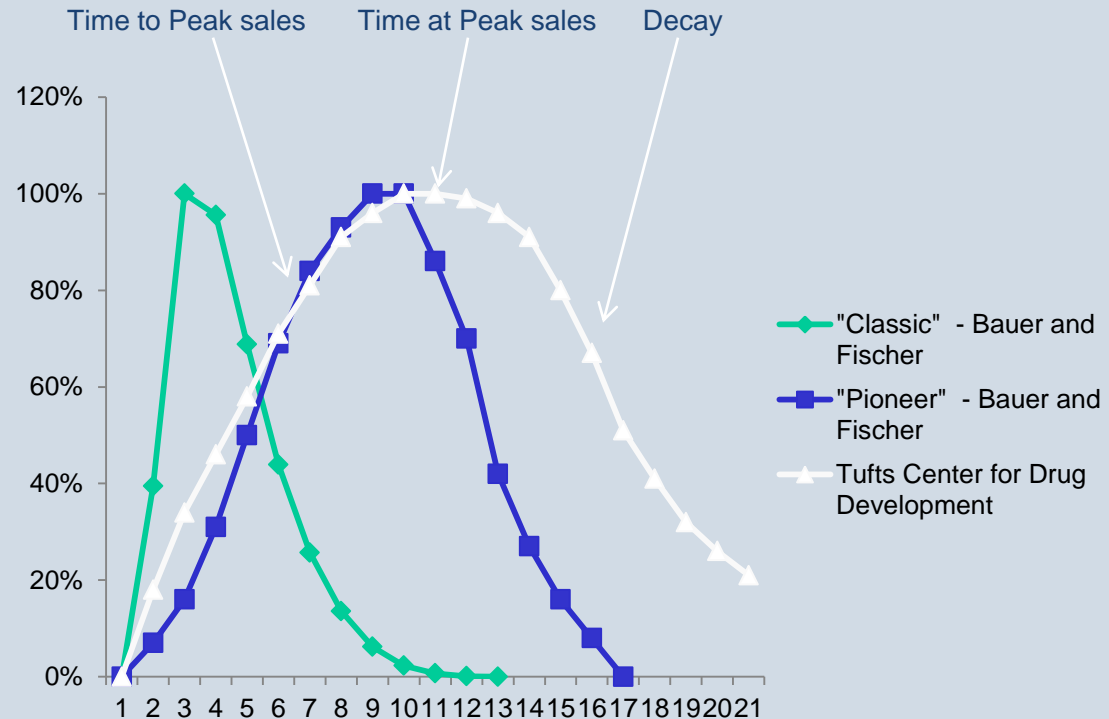
Methods used:

- Bottom-up approach
 - Based on primary market data
- Top-down approach
 - based on comparable products



Product Life Cycle

Market penetration:



A. Define Growth Phase (4-8 years)

B. Define Mature Phase (1-4 years)

C. Define Decay Phase (7-10 years)

Product Life Cycle



Which variables affect the Life Cycle?

1. Me-too drug or a pioneer
2. Competitive landscape
3. Physician response
4. Ease of reaching physicians
5. Need for physician training
6. Payor reimbursement
7. Pharmacoeconomic reimbursement

Bottom up approach



Sales Forecast

Western EU		2018	2019
Population (000's)		300'000	306'000
Incidence rate (%)	0.020%	60.000	61.200
Diagnosed population	70%	42.000	42.840
Population treated with drugs	80%	33.600	34.272
Compliance rate	90%	30.240	30.845
Addressable population		30.240	30.845
Market penetration rate (%)		18%	34%
Patient population		5.443	10.487
Market share		12%	
Price (EUR)		2000	
Sales Western EU (EUR 000's)		1'306	2'517
USA Sales		2'540	4'798
Japan Sales		392	755
Rest of the World (RoW) Sales		1'270	2'399
Total sales (EUR 000's)		5'508	10'469

Peak Sales

Value

USD 1bn => USD 8m

USD 0.7bn => USD 3m

USD 2bn => USD 25m

Discount rate



Used discount rate in rNPV:

- Early stage 12% - 28%
- Mid stage 10% - 22%
- Late stage 9% - 20%

Source: www.biostrat.dk

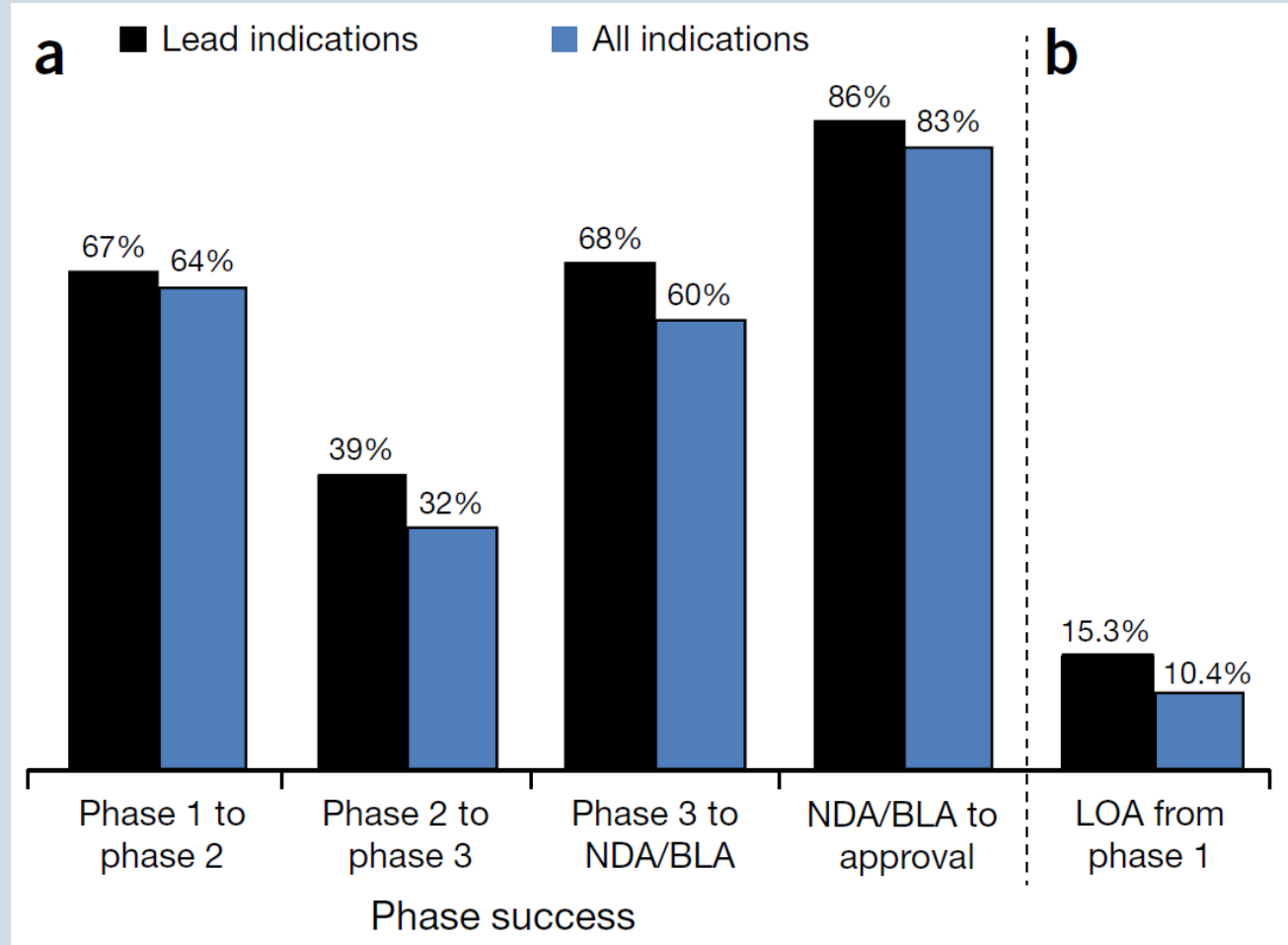
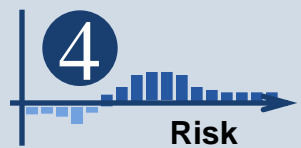
Cost of equity and non-development associated risks.

20% => USD 8m

25% => USD 2m

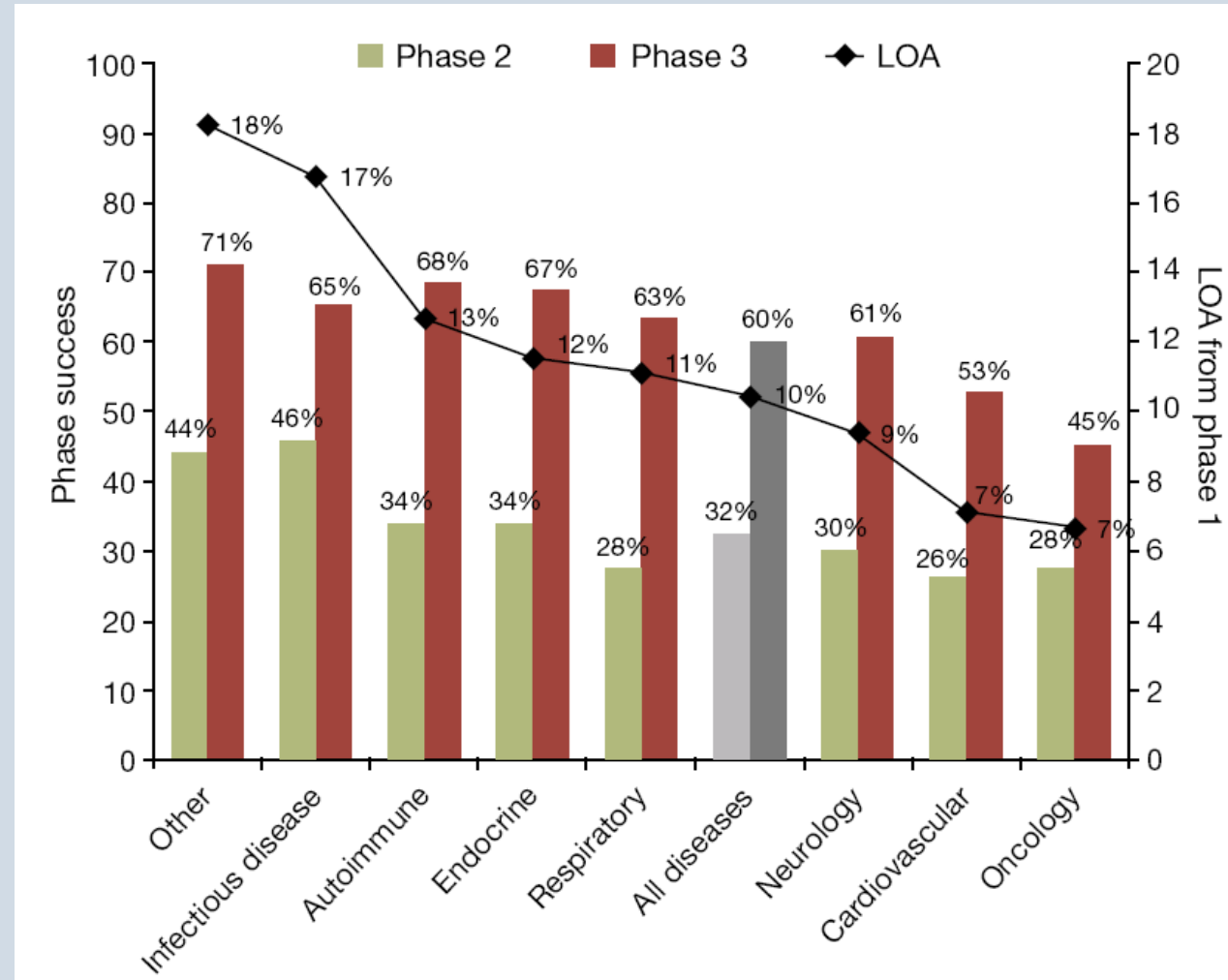
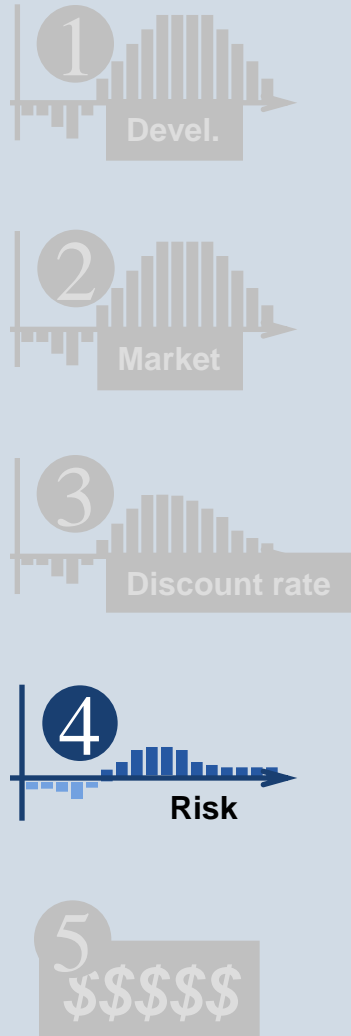
15% => USD 21m

Adjust for risk (II)



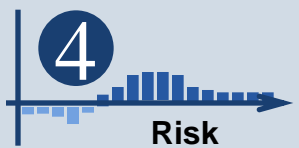
Source: Nature Biotechnology; Clinical development success rates for investigational drugs; January 2014
LOA: Likelihood of approval

Adjust for risk (I)



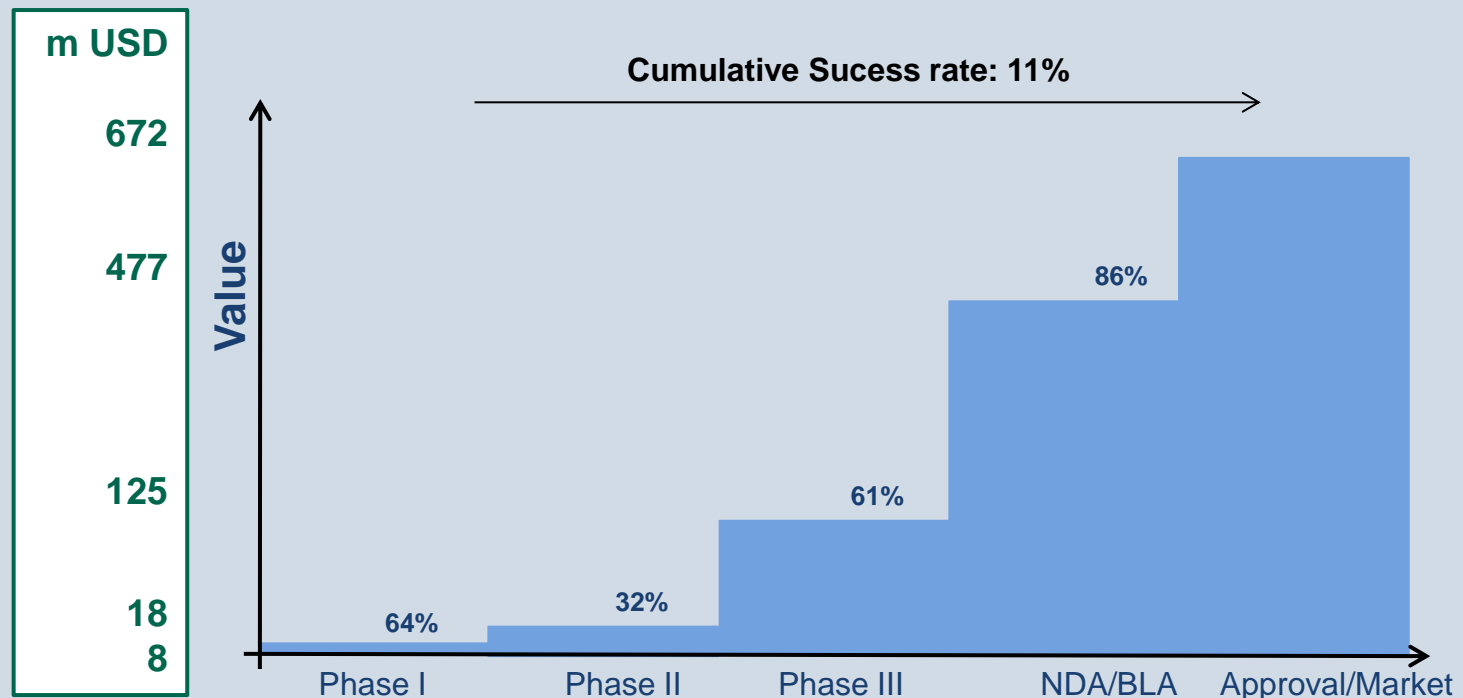
Source: Nature Biotechnology; Clinical development success rates for investigational drugs; January 2014
LOA: Likelihood of approval

Adjust for Risk (III)



The relation between Risk and Value

- Completion of a phase → Direct value increase



Sum Cash Flows

- Sum discounted, risk-adjusted yearly cash flows to a single value



5

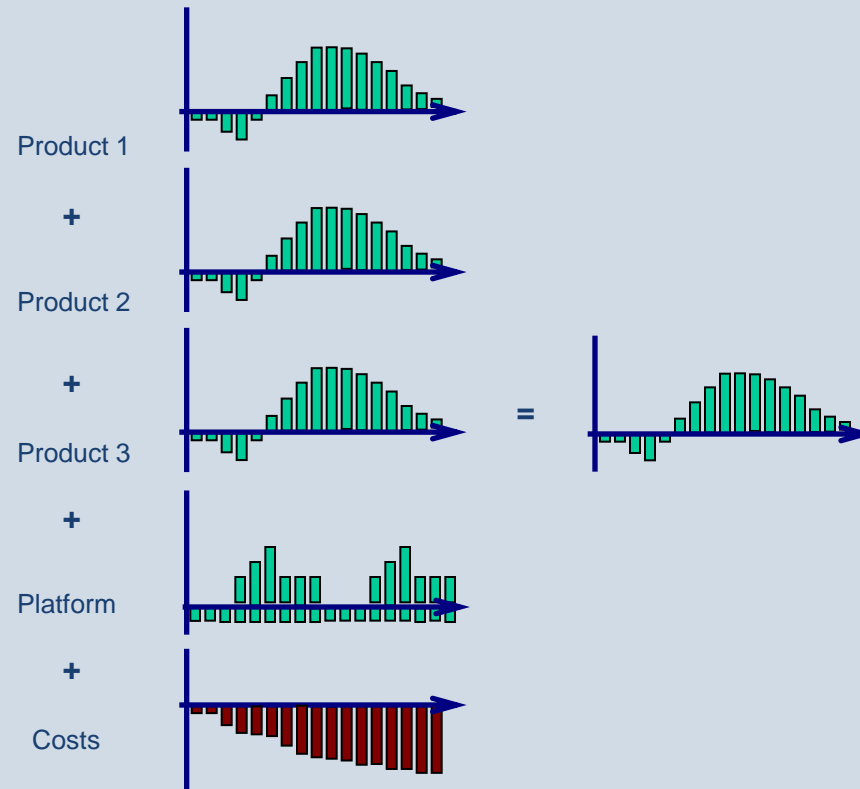
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YEAR	2017	2018	2019	2020	2021
Phase	P III	Approval	Market	Market	Market
DEVELOPMENT COSTS	-50'000	-2'500			
SALES			50'000	100'000	250'000
-Discounts, Returns, Allowances	0%	-	-	-	-
NET REVENUES (USD 000's)	-	-	50'000	100'000	250'000
Total Product Costs	-	-	-10'000	-20'000	-50'000
EBIT	-50'000	-2'500	40'000	80'000	300'000
Tax	0%	-	-	-	-
FREE CASH FLOW	-50'000	-2'500	40'000	80'000	300'000
DISCOUNTED CASH FLOWS	-43'478	-1'890	26'301	45'740	149'153
Stage	Phase III	Approval	Market	Market	
Cumulative success rate*	100%	75%	66%	66%	66%
RISK ADJUSTED CASH FLOWS	-43'478	-1,418	17'359	30'188	98'441
TOTAL PRODUCT VALUE	125'548				

*Success rate	Phase I	Phase II	Phase III	Approval
Per phase	100%	100%	75%	88%
Cumulative	100%	100%	75%	66%

1. Overview of product valuation
2. rNPV product valuation
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4. Deal Structure
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Example



Early stage company

Sum-of parts valuation

Total value of project

1. Overview of product valuation
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Structuring the deal

AIM: to develop a **fair** deal structure

rNPV



■ Pharma
■ Biotech

- Product value has to be shared
- The licensee (Pharma) is compensated for taking on risk
- The licensor (Biotech) receives payments and shares some of the risk and rewards
- The model inputs and assumptions are simple, understandable, and transparent

The rNPV valuation can help to understand the deal terms

Deal structuring process

1
\$\$\$\$\$

Determine Product **Value**



2

Handover

Determine handover time point



3

Deal terms

Determine preferred **Milestones** and **Royalties**



4

Deal terms

Negotiate terms

Timing of payments



- Front/ back-loading a deal can heavily influence deal structure
- Deal terms dependent on needs of both parties

In USD m	Payment of	rNPV* (or up-front)
Up-front	1 m	1 m
Finish Pre-clinical	1 m	0.44 m
Finish Phase I	1 m	70'000
Finish Phase II	1 m	17'000
Finish Phase III	1 m	8'000
Approval / Enter market	1 m	5'000
Royalties	1%	0.70 m

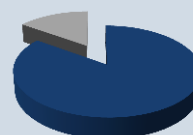
* Time value of money and Risk adjusted

Timing of payments (II)

- Two very different deal structures can look identical



Cash Flow



■ Pharma
■ Biotech

- Non-discounted, non-risk adjusted

rNPV



■ Pharma
■ Biotech

- 25 million upfront
- 300 million milestones
- 5% royalties

rNPV



■ Pharma
■ Biotech

- 5 million upfront
- 50 million milestones
- 12% royalties

1

2

Case Study



1) Case study reading time (10 min) 2) Valuation / Discussion

- A) Determine the current value of XC-71F.
- B) Would you accept the deal terms suggested by the biotech company?
- C) Develop a deal scenario that is fair for both parties.

THE VALUATION EXPERTS

Thank you for listening!

Slides available on www.venturevaluation.com

Tel : +41 (43) 321 86 60
Fax: +41 (43) 321 86 61
www.venturevaluation.com
p.frei@venturevaluation.com

Venture Valuation AG
Kasernenstrasse 11
8004 Zürich
Switzerland