asceni-on

Life Sciences into Business

jsb partners

global partners in life science transactions

Valuation and Negotiation

May 26th 2011, ASTP-conference, Stockholm

Agenda of Today

1. Introduction
2. Goals of the Workshop
3. Valuation Methods
4. Negotiation Framework
5. Case Study

Introduction: Anja Zimmermann

Ascenion

- Founded in 2001
- Focus on life sciences
- Marketing of >700 technologies and materials of public research institutions
  - Helmholtz Association
  - Leibniz Association
  - Hanover Medical School
  - TT in the NGFN
  - Mouse Genetics Cologne Foundation
- Team of 22 specialists with multiyear experience and sector specific expertise
  - Technology Managers (Scientists)
  - Analysts
  - Legal / Tax Advisors
- Offices in Munich, Berlin, Brunswick, Hamburg, Neuherberg, Hanover

Anja Zimmermann

- Analyst at Ascenion since 2001
- Focus on life science and economics: Biologist (PhD) and business economist
- Based in Munich office
- Responsible e.g. for
  - licensing projects (patented and non patented technologies),
  - Ascenion's spin off portfolio
  - valuation issues (NPV, etc.)

Short Introduction: Ulrich Pessara

Short CV

- 2004 – today: General Partner JSB Partners LP (Managing Director, Zug-Switzerland)
- 1999 – 2003: Cofounder / COO of Xantos Biomedicine, Munich
- 1991 – 1999: Director Molecular Medicine, Boehringer Mannheim / Hoffman – La Roche
- 1981 – 1991: PhD in Immunology/Molecular Genetics (Hanover, Cologne, Heidelberg, Strassbourg)

Overview on JSB Partners

- International transaction broker for the healthcare community doing licensing, M&A and financing transactions
- Deal volume since 2008 > US$ 2 billion
- Major offices in New York, Boston, Munich and Zürich
- Spin-off from MPM Capital/Boston in 1999

Introduction: Jörn Erselius

Short CV

- 2005 – today: Managing Director, Max Planck Innovation, Munich
- 2011 RTTP (Registered Technology Transfer Professional, ATTP)
- 2007 - 2011: Board Member ASTP
- 2002 – 2004: MBA Management, University of Applied Sciences Deggendorf
- 1991 – 2005: Patent- and Licensing Manager, Max Planck Innovation
- 1988 – 1991: PhD in Developmental Biology/Molecular Genetics (Heidelberg, Göttingen)

Overview Max Planck Innovation

- technology transfer agency of the Max Planck Gesellschaft (largest basic research organization in Germany)
- 130-150 invention disclosures / 80 patent applications per year
- license income/year: € 16-17 million (US$ 22-24 million)
- 90 Spin-offs since 1990

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Introduction: Goals of This Workshop

- **Valuation**
  - Understand several valuation techniques
  - Be able to use rNPV calculation technique
  - Get overview on relevant parameter required for rNPV valuation
  - Develop valuation of „Case Study“

- **Negotiation**
  - Understand negotiation processes in Biotech partnering
  - Respect „don‘ts“ and „dos“
  - Avoid major mistakes in Biotech partnering

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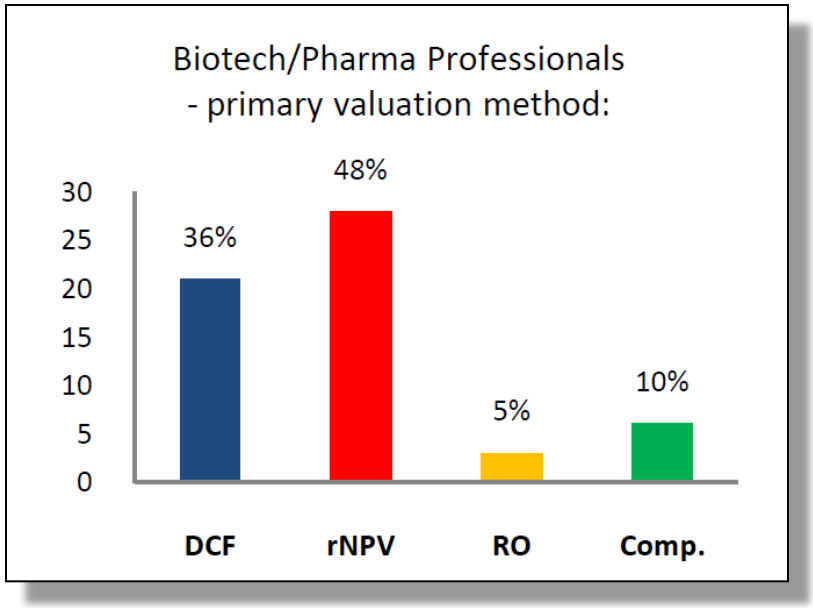
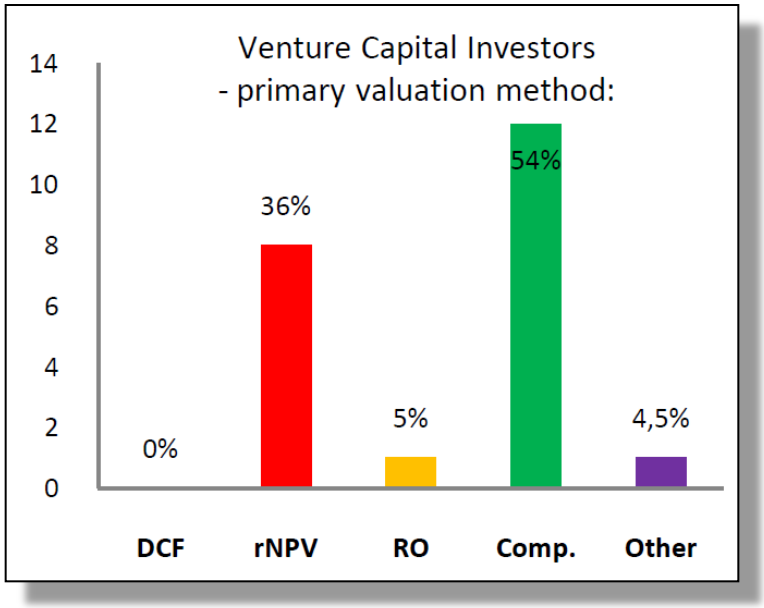
Project Valuation – What Pharma/Biotech or Venture Capital Professionals Use





Source: Biostrat Biotech Consulting (www.biostrat.dk)

Potential Valuation Methods

- „rule of the thumb“
- 25% rule
- Benchmarking
- Development costs
- Auction
- Sales Multiples
- Comparables
- DCF (Discounted cash flow)
- NPV (Net Present Value)
- Decision Tree
- Real Options

Relevant Valuation Methods

- „rule of the thumb" – common but not very professional
- 25% rule – based on out dated presumptions
- **Benchmarking – ok for some applications**
- Development costs – not applicable for governmentally funded research organisation
- Auction – hoped for but rarely if ever happening
- **Sales Multiples – IF there are sales**
- Comparables – good for real estate not good for biotech
- DCF (Discounted cash flow) – leaves out too many risks in our risky field
- **NPV (Net Present Value)**
- Decision Tree – required data in the biotech field can almost never be provided
- Real Options – too complicated and not widely accepted

Risk-Adjusted Net Present Value Calculation

- **Known at least since the 19th century**

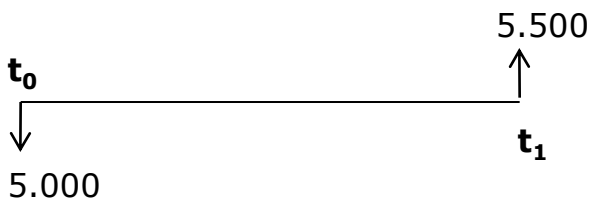
$$rNPV = -I_o + \sum_{t=1}^{T} \frac{rCF_t}{(1+r)^t}$$

I_0 = Investment into the project at time 0 (=CF_0)
rCF_t = Risk adjusted cash flow at time t
r = Discount rate
T = Endpoint of the project (if today is $t = 0$, T = duration of the project)

- **Most common valuation method in Pharma/Biotech**
- **Important tool when negotiating partnering agreements**
- **Requires knowledge of**
  - All costs required
  - All income to be generated
  - All risks involved
  - Inflation rate / Cost of capital
- **Therefore beware: „garbage in, garbage out"**

Background– Time Value of Money

A loan of 5.000 at 10% (i):



Future Value = 5.000 · (1+0,1) = 5.500

FV = PV · (1+i)

Present Value = 5.500 / (1+0,1) = 5.000

PV = FV / (1+i)

A dollar in your hand today has more value than a dollar tomorrow

Background – Present Value (Discounting)

Loan at 10% (i)

Period	t_0	t_1	t_2
Wealth	**100** → 100 (PV_0)	110 → $100 \cdot (1+i)$	**121** $100 \cdot (1+i)^2$

Future Value $FV = PV_0 \cdot (1+i)^n$

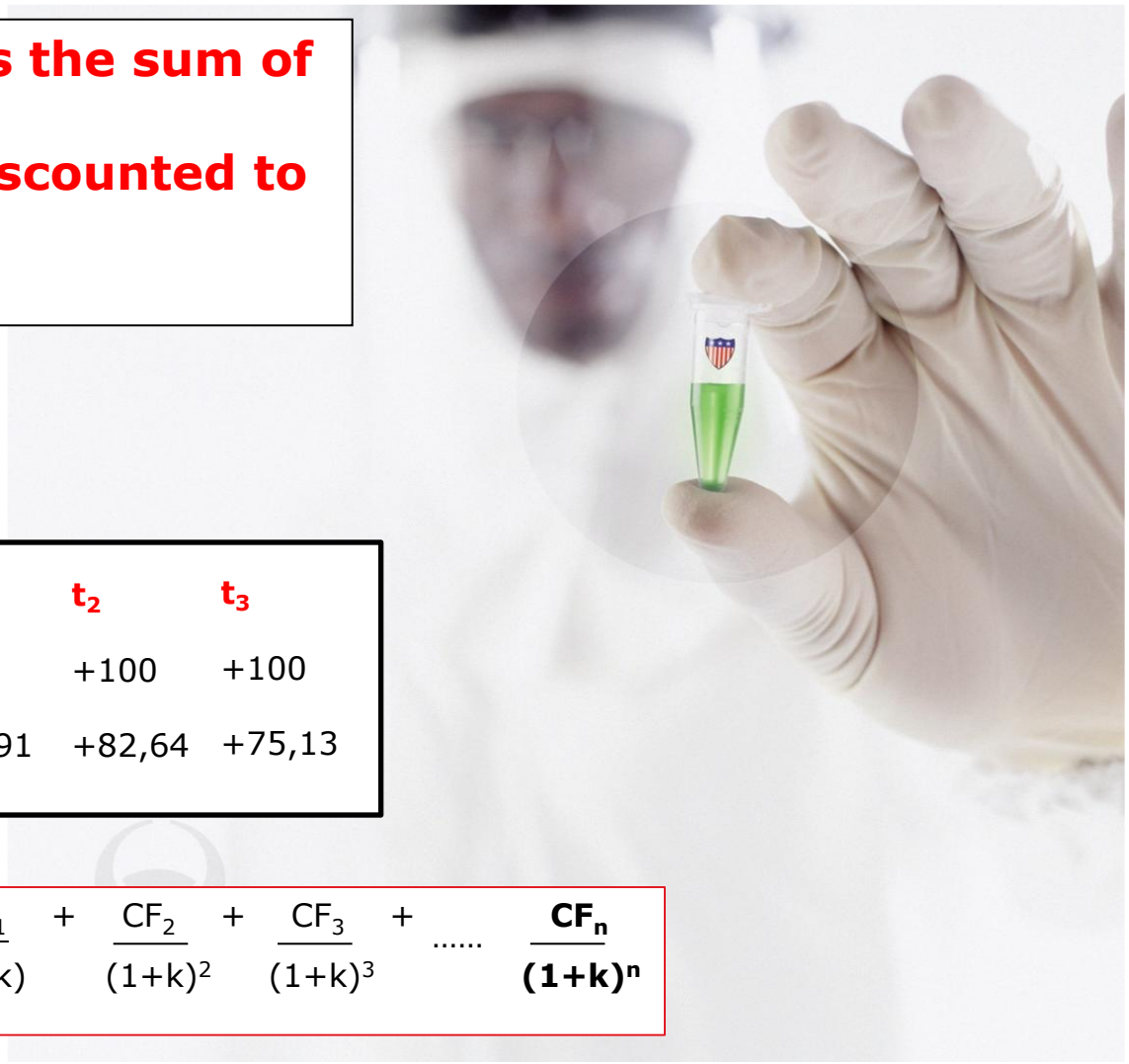
Period	t_0	t_1	t_2
Cash Flow	**82,64** $100/(1+i)^2$ ←	90,91 $100/(1+i)$ ←	**100**

Discounting

Present Value $PV = CF_n / (1+i)^n$

Background – Discounted Cash Flow (DCF) Analysis

The value of an asset is the sum of all future cash flows discounted to today



Period	PV	t_0	t_1	t_2	t_3
Cash Flows		+100	+100	+100	+100
Discount. CF	**+348,68**	+100	+90,91	+82,64	+75,13

Present Value $PV = CF_0 + \frac{CF_1}{(1+k)} + \frac{CF_2}{(1+k)^2} + \frac{CF_3}{(1+k)^3} + \ldots\ldots \frac{\mathbf{CF_n}}{\mathbf{(1+k)^n}}$

Background– Risk-Adjusted Net Present Value

Year	0	1	2	3	4	5	6
Expenses	($ 50,000)	($ 500,000)	($ 10,000)	($ 20,000)	($ 30,000)	($ 20,000)	($ 10,000)
Revenues			$ 100,000	$ 200,000	$ 300,000	$ 200,000	$ 100,000
Net CF	($ 50,000)	($ 500,000)	$ 90,000	$ 180,000	$ 270,000	$ 180,000	$ 90,000
Probability	100%	50%	50%	50%	50%	50%	50%
Risk adjusted CF	($ 50,000)	($ 250,000)	$ 45,000	$ 90,000	$ 135,000	$ 90,000	$ 45,000
Discount	100%	87%	76%	66%	57%	50%	43%
rpCF	($ 50,000)	($ 217,391)	$ 34,026	$ 59,176	$ 77,187	$ 44,746	$ 19,455
rNPV	($ 32,801)						

Praxis – Valuation in Biotech

Clinical Projects are Biotech's Primary Assets

<u>Uncertainties</u>:

Time, risk and cost

Parameters for biotechnology

Average risk mitigated (when beginning the phase):	Time to complete:	Number of clinical-trial subjects:
Preclinical: 10%		
Phase 1: 20%	Phase 1: 0.5–1 year	Phase 1: 20–80
Phase 2: 30%	Phase 2: 1.5 years	Phase 2: 100–300
Phase 3: 67%	Phase 3: 3.5 years	Phase 3: 1,000–5,000
FDA approval[4]: 81%	FDA approval: 1.5 years	

Costs:

Phase 1 and 2: Clinical trials (outsourced): $8,000–$15,000 per subject
Phase 3: Clinical trials (outsourced): $4,000–$7,500 per subject
Animal studies to support phase 1: ~$500,000
Animal studies to support phase 2: ~$1 million
Animal studies to support phase 3: ~$1.5 million
FDA approval: $0.8–$1.8 million+ ($300,000 for the Prescription Drug User Fee Act II fee and the remainder for preparation of the New Drug Application (NDA); NDA-preparation costs are highly variable and depend largely on the amount and the quality of data to be presented)

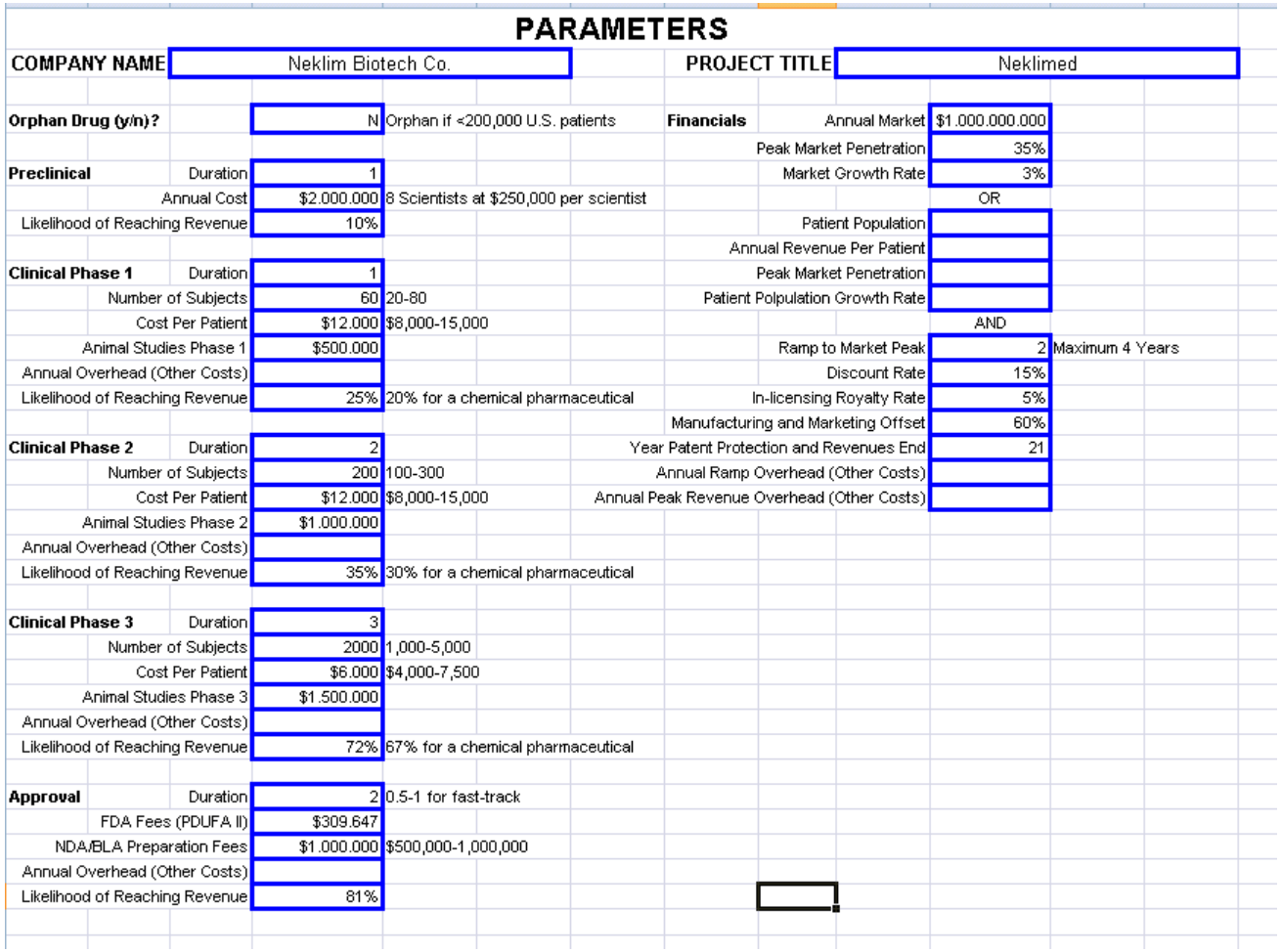
Financials:

Revenue reserved for manufacturing and marketing: 40–60% (choose the high end to justify a reasonable market percentage)

Discount rate (cost of capital for biotech firms[1]; R&D risk considered separately): 20%

nature biotechnology • VOLUME 19 • SEPTEMBER 2001 • *http://biotech.nature.com*

Praxis – Using Example Spreadsheets



PARAMETERS

COMPANY NAME		Neklim Biotech Co.		**PROJECT TITLE**		Neklimed	
Orphan Drug (y/n)?		N	Orphan if <200,000 U.S. patients	**Financials**	Annual Market	$1.000.000.000	
					Peak Market Penetration	35%	
Preclinical	Duration	1			Market Growth Rate	3%	
	Annual Cost	$2.000.000	8 Scientists at $250,000 per scientist			OR	
	Likelihood of Reaching Revenue	10%			Patient Population		
					Annual Revenue Per Patient		
Clinical Phase 1	Duration	1			Peak Market Penetration		
	Number of Subjects	60	20-80		Patient Polpulation Growth Rate		
	Cost Per Patient	$12.000	$8,000-15,000			AND	
	Animal Studies Phase 1	$500.000			Ramp to Market Peak	2	Maximum 4 Years
	Annual Overhead (Other Costs)				Discount Rate	15%	
	Likelihood of Reaching Revenue	25%	20% for a chemical pharmaceutical		In-licensing Royalty Rate	5%	
					Manufacturing and Marketing Offset	60%	
Clinical Phase 2	Duration	2			Year Patent Protection and Revenues End	21	
	Number of Subjects	200	100-300		Annual Ramp Overhead (Other Costs)		
	Cost Per Patient	$12.000	$8,000-15,000		Annual Peak Revenue Overhead (Other Costs)		
	Animal Studies Phase 2	$1.000.000					
	Annual Overhead (Other Costs)						
	Likelihood of Reaching Revenue	35%	30% for a chemical pharmaceutical				
Clinical Phase 3	Duration	3					
	Number of Subjects	2000	1,000-5,000				
	Cost Per Patient	$6.000	$4,000-7,500				
	Animal Studies Phase 3	$1.500.000					
	Annual Overhead (Other Costs)						
	Likelihood of Reaching Revenue	72%	67% for a chemical pharmaceutical				
Approval	Duration	2	0.5-1 for fast-track				
	FDA Fees (PDUFA II)	$309.647					
	NDA/BLA Preparation Fees	$1.000.000	$500,000-1,000,000				
	Annual Overhead (Other Costs)						
	Likelihood of Reaching Revenue	81%					

J. Stewart et al., Putting a Price on Biotechnology. Nature Biotechnology 2001. 19:813.

Praxis – Pros & Cons

Pro:

- Need for data research
- Creates transparency
- Easy to use

Con:

- Only as good as input
- Very sensitive to discount rates, peak sales and risks!

Fact to Consider

- **rNPV very much dependent on input data; so do your analysis well**
- **rNPV very much dependent on three variables accounting more than 20% variability each:**
  - Discount factor,
  - Sales numbers and
  - Risk factors for the individual development phases
- **So whatever you calculate today, will be wrong in the future!!**

Predicting the Future: Famous But Wrong Predictions by the Experts

- ***"Louis Pasteur's theory of germs is ridiculous fiction".*** *-- Pierre Pachet, Professor of Physiology at Toulouse, 1872*
- ***"Heavier-than-air flying machines are impossible."*** *-- Lord Kelvin, president, Royal Society, 1895.*
- ***"I think there is a world market for maybe five computers."*** *-- Thomas Watson, chairman of IBM, 1943*
- ***"There is no reason anyone would want a computer in their home."*** *-- Ken Olson, president, chairman and founder of Digital Equipment Corp., 1977*
- ***"640K ought to be enough for anybody."*** *-- Bill Gates, 1981*
- ***"$100 million dollars is way too much to pay for Microsoft."*** *-- IBM, 1982*

Prediction of Drug Sales Potential

Product	Manufacturer	Use	Estimated Peak Sales (2004)	Sales 2009*
Avastin	Genentech	Cancer	**3000**	**5900**
Exanta	AstraZeneca	Thrombosis	**1300**	**0**
Alvesco	Altana, Aventis	Asthma	**1200**	**85**
Arcoxia	Merck	Osteoarthritis	**2500**	**377**
Caduet	Pfizer	Hypertension, hypercholesterolemia	**1090**	**590**
Cymbalta	Lilly	Depression	**2200**	**3000**
Zocor/Zetia	Merck, Schering-Plough	Cholesterol	**3000**	**6600**
Genasense	Genta	Malignant melanoma	**900**	**0**
Lyrica	Pfizer	Neuropathic pain	**2000**	**2900**
Spiriva	Boehringer Ingelheim, Pfizer	Pulmonary disease	**1340**	**3300**

M. Gröppel, 4SC (derived from Humphreys, A. (2004) 'Future Blockbusters', *MedAdNews, January, 1–12;* *Peak Sales 2009 according to Medtrack

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Negotiation: Essentials of a Successful Partnering Process

- **Preparation is of key importance**
  - Understand interests on the table
  - Selling documentation
  - Unique selling point / competitive advantage
- **Define clear process timelines**
  - Internal and external coordination
  - Generation of competition
- **Follow process and timelines and always keep control**
  - Establish "give and take" scenario
  - Generate competition
- **Establish trust**
  - Never oversell
  - Focus on involved persons
  - Proactively present weak spots and offer solutions
- **Generate win-win solutions**
  - For most deals, value generation starts at closing
  - Stay involved in further development

Negotiation: Managing a Successful Partnering Process

INITIAL CONTACT WAVE

CONFIDENTIAL PHASE

TERM SHEET PHASE

- Model value of alternative bids
  - Understand incoming offers
  - Compare incoming offers
  - Prioritize offers for decision making
- Confirm capabilities of interested parties
  - Receive capability presentations
  - Understand future plans with asset(s)
- Support due diligence
  - Enable data exchange
  - Keep track record for all exchanged information (reduces later reps and warranties in licensing contracts)
- Steer towards appropriate confirmed offers
  - Keep all parties at similar development level
  - Receive offer at the predefined milestone

Partnering & Negotiation: Key Acpects

- When?
- Where?
- Which team?
- planning
- attitude and language (cross cultural topics, how to work under pressure, etc.)
- Point by point
- Listen
- Prepare a draft + sum up negotiations in writing
- Options for mutual gain
- Know your BATNA (best alternative to a negotiated agreement)

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Case study

- **Biopharmaceutical drug, inhibiting angiogenesis („Bludex")**
- **Ready to enter phase I**
- **Potential indications: Colon Carcinoma (breast ca. as upside potential)**
  - 10% market reach on US market
  - US$ 30,000 annual treatment costs
  - Annual incidence Colon Ca. in US: 120.000 (today)
  - IP coverage until 2025
  - Discount factor: 20%
- **Questions to be answered:**
  - What will be the peak sales potential in USA?
  - What is the current rNPV for USA?
  - What is happening when you have to half the market price?

Case study cont.

- **For a general overview: http://web.mit.edu/biostrategy/files/031204_DiMasi_Slides.ppt**
- **For incidence/mortality numbers e.g. http://globocan.iarc.fr/**
- **For clinical trials: e.g. http://clinicaltrials.gov/ct2/info/understand**
- **For discount factors e.g: http://www.avance.ch/newsletter/docs/Discount_1.pdf**

Thank You!