



***DETERMINATION OF RISKS – WHAT SHOULD BE TAKEN INTO  
CONSIDERATION  
in Biotech and Pharma industries***



**Alain KAISER**

# Speaker's resume: Alain KAISER

## Professional Specialities:

**Financial evaluations of intellectual property rights**

**Judicial expert - Court of Appeal of PARIS – damages estimations in counterfeiting and passing off expertise**

**Strategy and financial evaluations of IP in different contexts :negociations taxes audits...**

**Consultant for industriels, lawyers or patent attorneys**

**Author of « L'évaluation de la PI » chez Lextenso**

**Articles : Les Nouvelles LES, DECIDEURS JURIDIQUES, La Tribune, Les Echos, Economie et Comptabilité, Echanges, Option Finance, La Revue des Marques, Les Echos HEC INPI « Les Entretiens de Paris »,« Securitization », « Patent valuations : methods and issues », working paper CEPN**

**Book : Financial valuation of technology assets (L'évaluation financière des actifs technologiques) lextenso-editions.fr ; lgdj.fr ; fnac.com et amazon.fr - code ISBN 978-2-297-06044-8**

## Professional career :

**Partner founder of IP TRUST patent attorney law firm**



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# **ISSUE I : IDENTIFY THE RISKS**

# USUAL RISKS FOR A STANDARD BUSINESS :

The 10 most common reasons for start up failures :

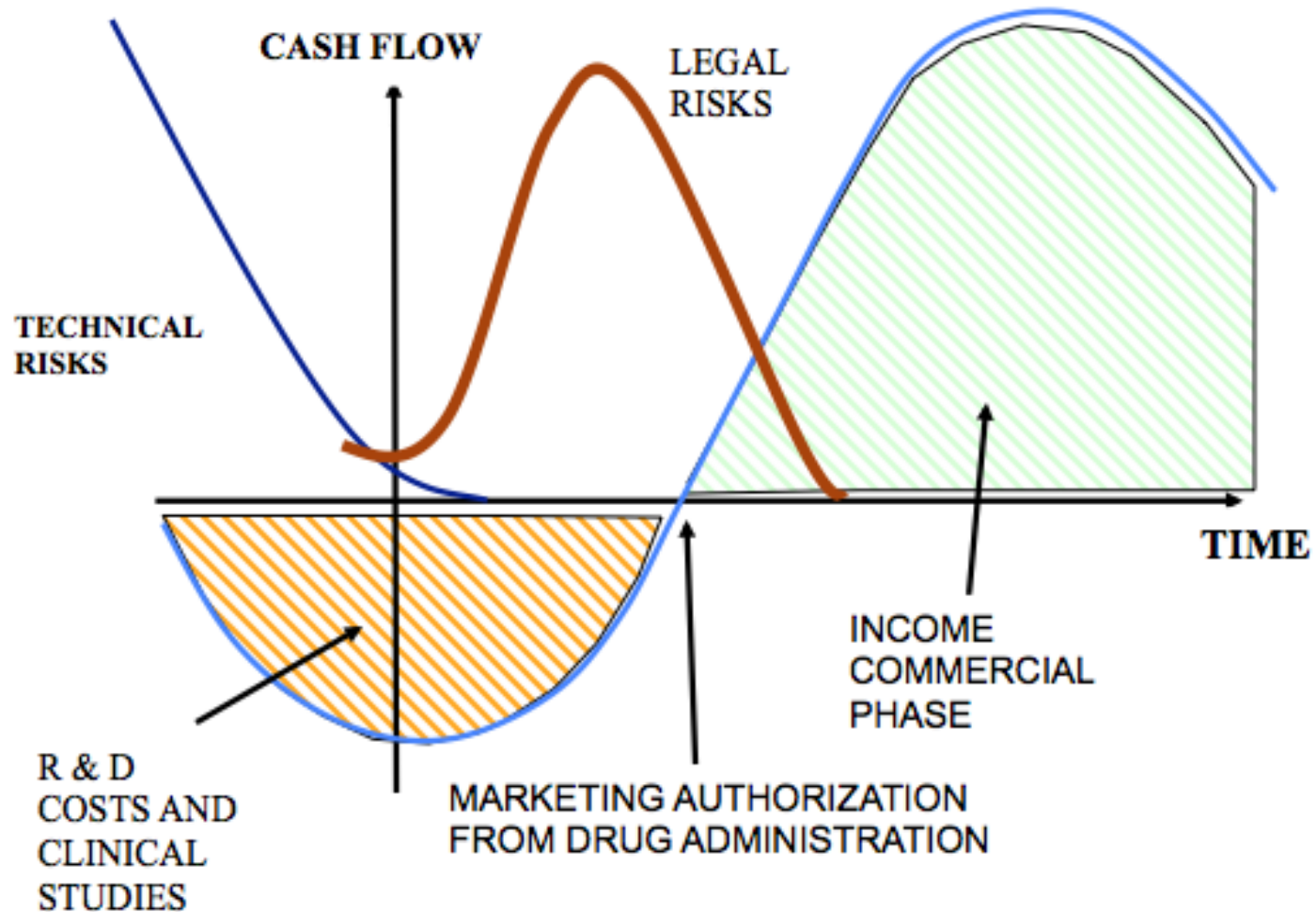
- **Solving an interesting problem instead of solving problems of a real market need**
- **Lack of cash bad management of resources**
- **Not the right team**
- **Too much competition, being blind to what happens elsewhere**
- **Inadapted selling price and poor economic model**
- **Bad product because of ignorance of the basic needs of customers**
- **Bad marketing strategy**
- **Ignorance of customer feedback**
- **Bad timing either marketed prematurely or too late**
- **Regulation changes (it takes few years to adapt the products to new regulations)**

# USUAL RISKS FOR A BIOTECH BUSINESS :

The 10 most common reasons for biotech start up failures :

- risks of misconceiving the technology
- **risks of failure at any point in time at each clinical stage**
- risks of not meeting the regulations needs in some countries
- risks of global economic or regulatory events influencing the obtention of the MA
- risks of competition developing a better product or launch on the market earlier
- risks of withdrawal of the drug by authorities and the stopping of the exploitation at any point in time (for instance authorities suspect a compound to be dangerous inside the drug )
- risks of doctor's errors in the prescription of the drug
- risks of death of patients due to drug incompatibilities
- **IP and legal risks**
- Risks of overspending in R&D

# RISKS EVOLUTION IN TIME :





## **ISSUE II : MEASURING THE SPECIFIC RISKS OF BIOTECHS**



# **LEGAL RISKS :**

**Genentech (US subsidiary of Roche) filed a lawsuit against Pfitzer blaming it for the violation of 40 of it's patents, one being a patent on it's 3 anticancers flagship HERCEPTIN.**

**HERCEPTIN generates around CHF 2.5 billions (5% of Roche's revenues)**

**Risks estimated by financial analysts is at about \$ 4 billion due to the arrival of cheaper versions of HERCEPTIN RITUXAN and AVASTIN**

# **LEGAL RISKS FOR A BIOTECH :**

**Biotech negotiates with a Big Pharma a 10% Royalty rate and Big Pharma will spend all R&D and clinical studies for Phase III and will assume the MA expenses.**

**Legal Analysis revealed that the Biotech patents are dependent on a patent belonging to another Biotech KYO**

**Biotech valuation depends on : the negotiation with Bigpharma for the whole technology and the negotiation with KYO for the exploitation of KYO patent**

# LEGAL RISKS FOR A BIOTECH : patent analysis

KYO	Intrinsic validity	Extrinsic validity	Geographic scope	Technical scope	Dependence	Scoring	Weight	total
EP 1 xxx xxx	0,80	0,90	1,00	0,90	1,00	0,92	3	2,751
Total							3,0	2,751

KYO

cluster weight  
in % according  
legal &  
technical  
analysis

35,0%

BIOTECH	Intrinsic validity	Extrinsic validity	Geographic scope	Technical scope	Dependence	Scoring	Weight	total
Patent Family 1 « Anti-G »	1,00	0,50	1,00	1,00	1,00	0,87	3	2,612
Patent Family 2 « Anti-G »	0,20	0,60	1,00	0,30	0,30	0,40	1	0,404
Patent Family 3 « Anti-G »	0,20	0,40	0,80	0,30	0,30	0,36	1	0,357
Patent Family 4 « Anti-G »	1,00	0,70	1,00	0,70	1,00	0,87	2	1,734
Total							7,00	5,107

BIOTECH

65,0%

100,0%

# LEGAL RISKS FOR A BIOTECH : revenues from royalties

## MARKET Antibodies Anti-G

BIG PHARMA Point of view

Years	SALES	Royalties costs	Costs of goods sold & SG&A	Op Income	Op Income after taxes	Risks adjusted Op Income	Cash phase III investment	risks ajusted Cash phase III investment	Cash Flow
2019	0	0	0	0	0	0	0	0	0
2020	0	0	0	0	0	0	0	0	0
2021	0	0	0	0	0	0	-16 500	-9 900	-9 900
2022	0	0	0	0	0	0	0	0	0
2023	0	0	0	0	0	0	-1 600	-960	-960
2024	15 000	1 500	7 500	6 000	4 200	2 520	0	0	2 520
2025	30 000	3 000	15 000	12 000	8 400	5 040	0	0	5 040
2026	45 000	4 500	22 500	18 000	12 600	7 560	0	0	7 560
2027	60 000	6 000	30 000	24 000	16 800	10 080	0	0	10 080
2028	70 000	7 000	35 000	28 000	19 600	11 760	0	0	11 760
2029	80 000	8 000	40 000	32 000	22 400	13 440	0	0	13 440
2030	90 000	9 000	45 000	36 000	25 200	15 120	0	0	15 120
2031	100 000	10 000	50 000	40 000	28 000	16 800	0	0	16 800
2032	100 000	10 000	50 000	40 000	28 000	16 800	0	0	16 800
2033	100 000	10 000	50 000	40 000	28 000	16 800	0	0	16 800
NPVs (ke)	286 099	28 610	143 049	114 440	80 108	48 065	-14 187	-8 512	39 552

Discount Rate	8%
Royalties negotiated with Biotech	10%

Risks	60%	SUCCESS RATE
Tax rate	30%	
Big Pharm Operating	50,00%	

# LEGAL RISKS FOR A BIOTECH : revenues sharing with KYO

## MARKET Antibodies Anti-G

### BIOTECH point of view

Years	Royalties received from Big pharma	Royalties to pay to KYO	Net royalties received by Biotech	Risks adjusted Net royalties received by Biotech
2019	0	0	0	0
2020	0	0	0	0
2021	0	0	0	0
2022	0	0	0	0
2023	0	0	0	0
2024	1 500	525	975	585
2025	3 000	1 050	1 950	1 170
2026	4 500	1 575	2 925	1 755
2027	6 000	2 100	3 900	2 340
2028	7 000	2 450	4 550	2 730
2029	8 000	2 800	5 200	3 120
2030	9 000	3 150	5 850	3 510
2031	10 000	3 500	6 500	3 900
2032	10 000	3 500	6 500	3 900
2033	10 000	3 500	6 500	3 900
<b>NPVs (ke)</b>	<b>28 610</b>	<b>10 013</b>	<b>18 596</b>	<b>11 158</b>

**Discount Rate** 8%

**Royalties negotiated with KYO** 35,0%

**Risks** 60% **SUCCESS RATE**

**Tax rate** 30%

# CLINICAL PHASES RISKS FOR A BIOTECH: OPTIONS

## ASSUMPTIONS

R&D costs phase 2	-10
R&D costs phase 3	-5
Probabilities	
Phase 2 Success rate	50%
Phase 3 Success rate	50%
	100%
NPV if success :	100
risk free rate	1%

# CLINICAL PHASES RISKS FOR A BIOTECH: STATISTICS

- Famous DiMasi statistics : « risks in new drug development »
- <https://clinicaltrials.gov/ct2/resources> ClinicalTrials.gov
- <http://guides.lib.uw.edu/hsl/data/findclin> Health Science Library Univ Washington
- And many others

# CLINICAL PHASES RISKS FOR A BIOTECH: OPTIONS



- **Classic NPV**
- **rNPV**
- **Monte Carlo Simulation**
- **Decision Tree Analysis**
- **ROV**



# CLINICAL PHASES RISKS FOR A BIOTECH: OPTIONS

	NPV	NPV with high discount	rNPV	ROV Black & Scholes model	Decision Tree
Discount rate	10%	70%			
<b>NPV</b>	100 €	36 €	100 €		
INVESTMENT Phase 2	10	10	10		
INVESTMENT Phase 3	5	5	5		
<b>TOTAL</b>	<b>86,8 €</b>	<b>28,5 €</b>			
<i>Success probability phase 2</i>			50%		
Adjusted NPV Phase 2			50,0 €		
Present value of Investments Phase 2			-9,9 €		
Adjusted NPV - Investment Phase 2			40,1 €	40,10 €	
<i>Success probability phase 3</i>			50%		
Ajusted NPV Phase 3			20,1 €		
Present value of Investments Phase 3			-4,9 €		
<b>TOTAL</b>			<b>15,15 €</b>	<b>15,10 €</b>	<b>15,15 €</b>

# CLINICAL PHASES RISKS FOR A BIOTECH : NPV

DISCOUNT RATE						10%
NPV	Y1	Y2	Y3	Y4	Y5	
Revenues			15	31,8	80	NPV 100,02 €
Investments	-10	-5				-13,22 €
<b>TOTAL</b>						86,80 €

# CLINICAL PHASES RISKS FOR A BIOTECH

## : NPV high discount rate

DISCOUNT RATE						70%
NPV	Y1	Y2	Y3	Y4	Y5	
Revenues			15	31,8	80	NPV 36,11 €
Investments	-10	-5				-7,61 €
<b>TOTAL</b>						<b>28,50 €</b>

# CLINICAL PHASES RISKS FOR A BIOTECH

## : rNPV

Discount rate  
**NPV**

INVESTMENT Phase 2  
INVESTMENT Phase 3

**TOTAL**

*Success probability phase 2*

Adjusted NPV Phase 2

Present value of Investments Phase

Adjusted NPV - Investment Phase 2

*Success probability phase 3*

Ajusted NPV Phase 3

Present value of Investments Phase

**TOTAL**

**rNPV**

100 €

10

5

50%

50,0 €

-9,9 €

40,1 €

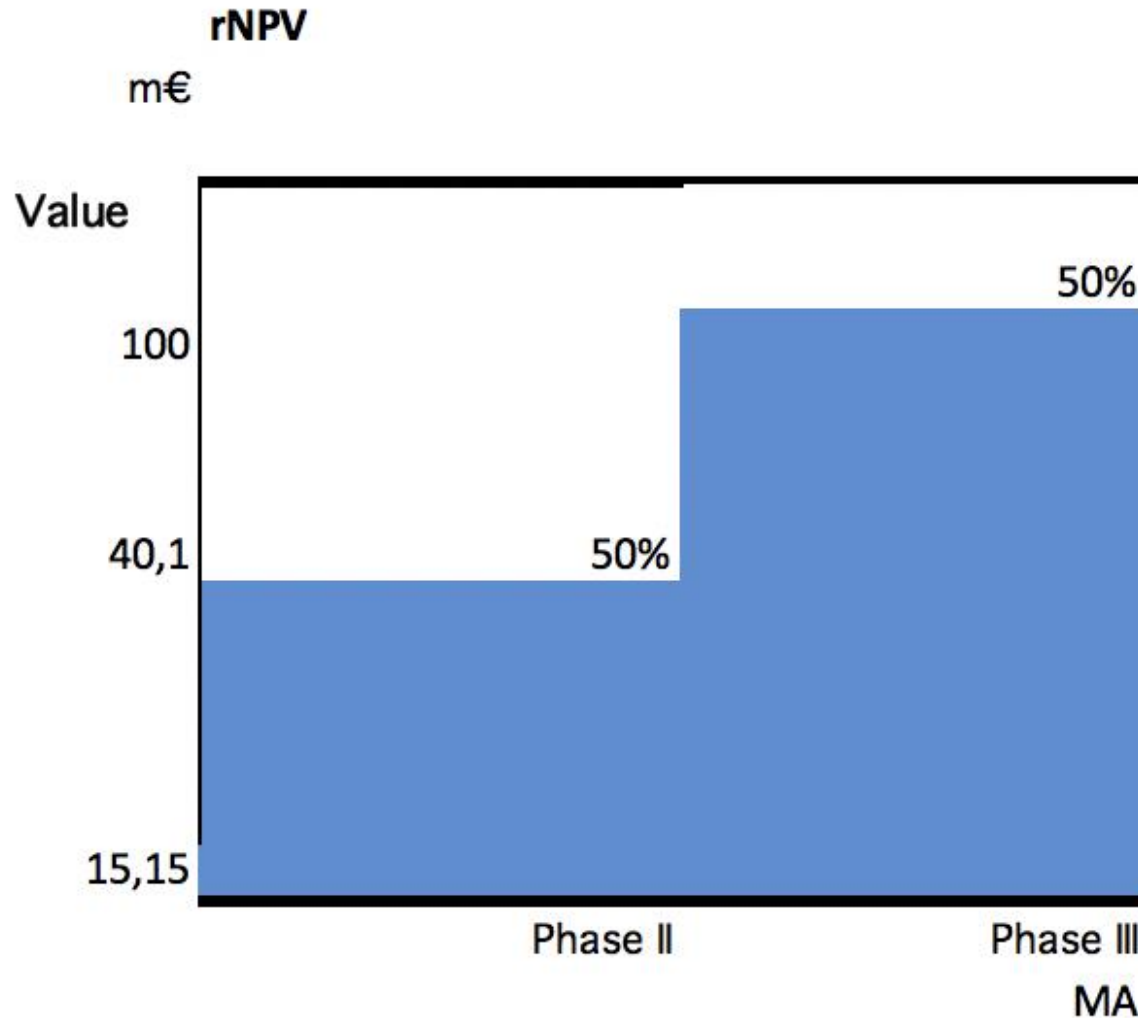
50%

20,1 €

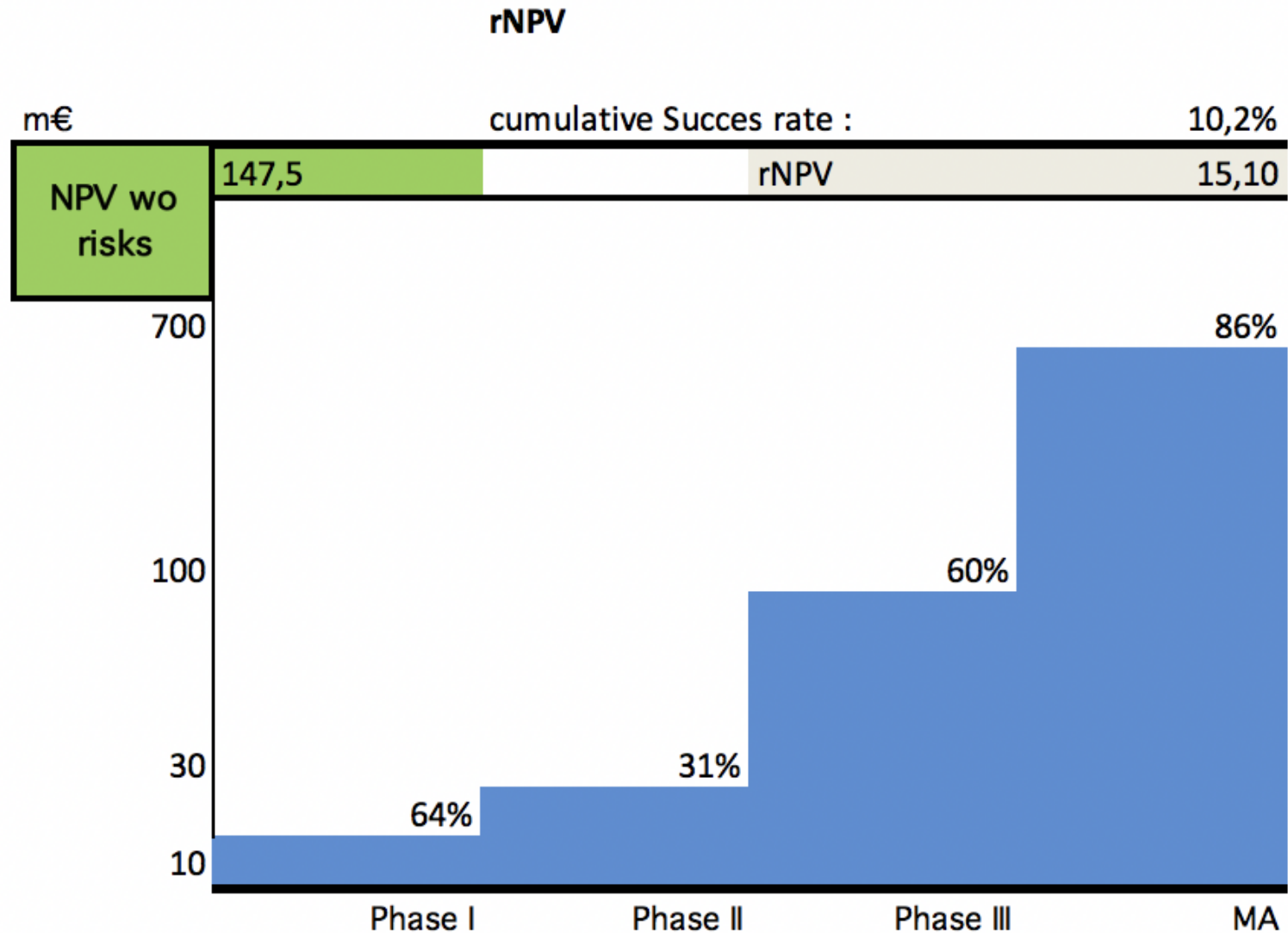
-4,9 €

**15,15 €**

# CLINICAL PHASES RISKS FOR A BIOTECH:



# CLINICAL PHASES RISKS FOR A BIOTECH:



# CLINICAL PHASES RISKS FOR A BIOTECH : ROV

Input Data	(in millions of €)
Today's Potential Value	100,00 €
Suces probability	50% <b>S</b>
Additional Required Investment	10,00 € <b>X</b>
Years to maturity	1,00 <b>T</b>
Risk-free rate	1,0% <b>r</b>
Volatility	25,0% <b>v</b>

European call value	40,10 €	call value
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**9,3753**

**9,1253**

# CLINICAL PHASES RISKS FOR A BIOTECH : ROV

Input Data	(in millions of €)
Today's Potential Value	40,10 €
Suces probability	50% S
Additional Required Investment	5,00 € X
Years to maturity	1,00 T
Risk-free rate	1,0% r
Volatility	25,0% v

European call value

15,10 € call value

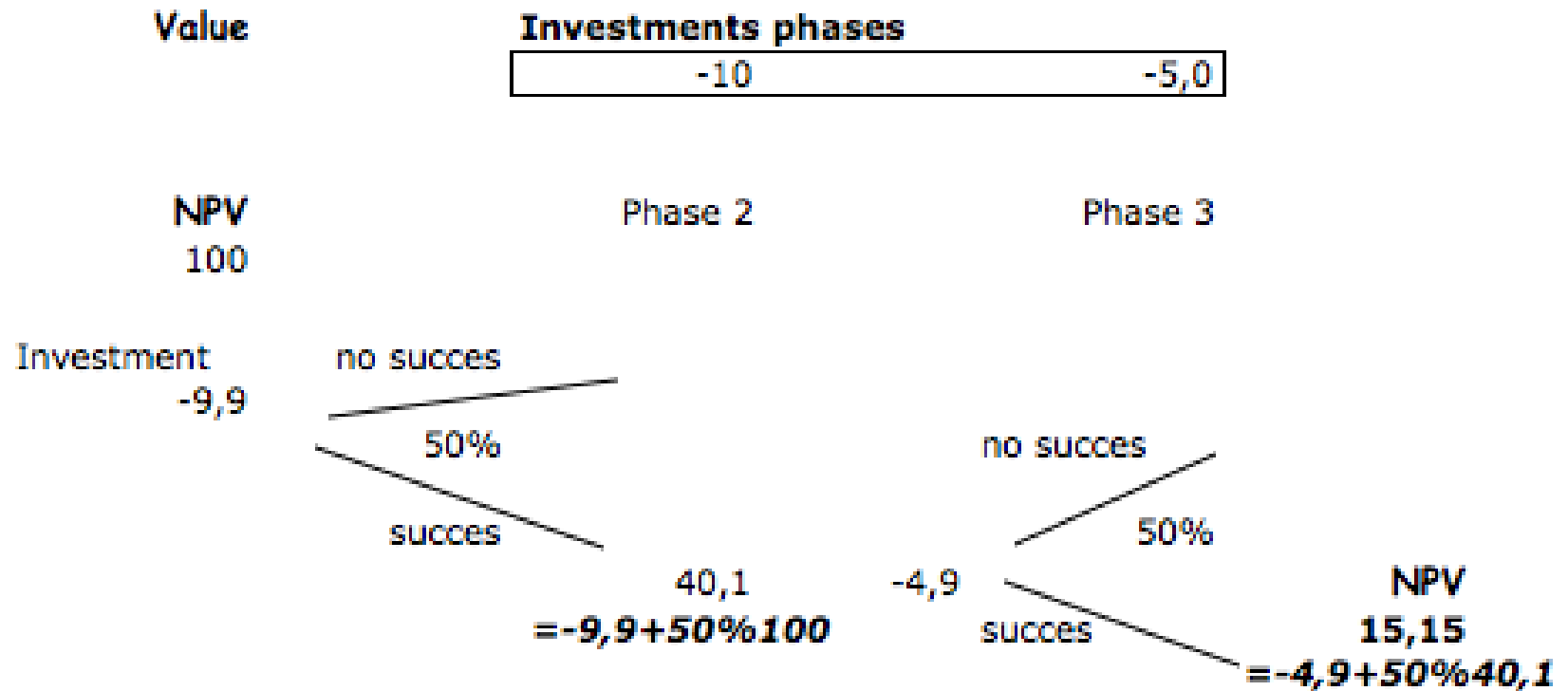
8,4927

8,2427



# CLINICAL PHASES RISKS FOR A BIOTECH

## DECISION TREE

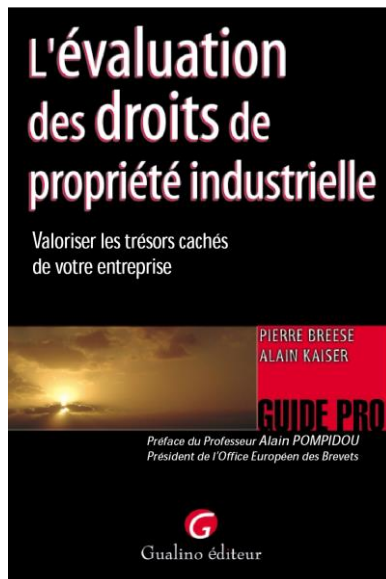


# VALUING A Biotech with ROV :

What ROV does :

- Flexibility in changes of management decisions
- Better measurements of risks
- Better adapted to high investments and long term returns
- Take into account the uncertainty
- Take into account strategic decisions
- Incorporates the possibilities to abandon the project

# Thank you for your attention



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« L'évaluation des droits de propriété industrielle »

Chez LEXTENSO- 2014

« L'évaluation financière des actifs technologiques »

Chez LGDJ- 2019