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Full Strategic Real Options Valuation in Pharmaceuticals

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Outline

Introduction

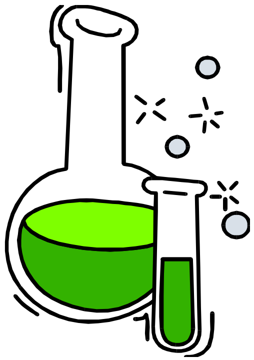
S-ROV™ Process

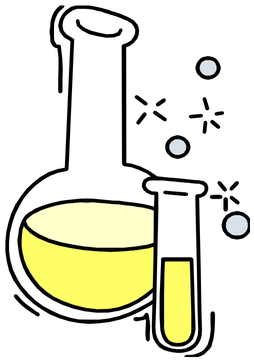
Summary of main Results

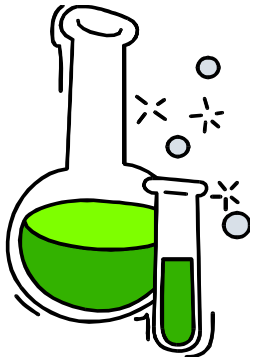
PVGO Analysis

Introduction

1. Project Characteristics
2. Background: The Company and its Strategy
3. Therapeutic areas and Product Pipeline







Project Characteristics

Goal → Estimate MediGene's target value applying Strategic Real Options Valuation (S-ROV™)

Input → MediGene's standard DCF valuation, company strategy, market and technical risk

Process → Decompose MediGene's DCF in a sequence of managerial
decisions that can be considered as Real Options

Output →
- MediGene's target equity value
- MediGene's value of growth opportunities
- MediGene's optimal follow-up strategic plan

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Background: The Company and its Strategy

Platform Technologies

- Exploit existing platform technologies (cardiac and oncology) to develop innovative products
- Expand portfolio of platform technologies

Research & Development

- License- in and acquire innovative products
- Strategic alliances and out-license platform technologies

Manufacturing

- Maintain in-house process development expertise while outsourcing commercial manufacturing

Therapeutic Areas and Product Pipeline

Indication	Technology	Project	Status and Plans					Potential Sales
			Research	Pre-clinic	Clinical Phase I	Clinical Phase II	Clinical Phase III	
Genital Warts	-	Polyphenon TME					ongoing	> 50
Congestive Heart Failure	ITD	Etoxomir				ongoing		>> 500
Brain Tumor	HSV	G207				Q3 2001		> 300
Cervical Cancer	CVLP	CVLP-vaccine (Schering AG)			ongoing			> 250
Liver Metastasis	HSV	NV1020			ongoing			> 200
Malignant Melanoma		rAAV -vaccine (Aventis)			Q1 2001			> 200

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S-ROV™ Process*

1. **DCF ANALYSIS**
2. **IDENTIFY REAL OPTIONS**
3. **ESTIMATE INPUT PARAMETERS**
4. **EXPAND REAL OPTIONS ANALYSIS**
5. **FULL S-ROV™**

Calculate DCF for each product thus assuming committed investment decisions

Execute Real Options analysis to identify options that are embedded in the Base DCF.
Create Option Map.
Analyze interactions among options.

Identify main value drivers (major underlying uncertainties).
Estimate Real Options input parameters

Expand Real Options analysis to capture additional opportunities

Execute a full S-ROV´™ to calculate company´s target value using Real Options Modular Engine (R.O.M.E.).
Conduct a sensitivity analysis.
Give strategic recommendations

* An AD-HOC document has been developed to provide details of each step and make the S-ROV™ process fully and easily replicable for other cases

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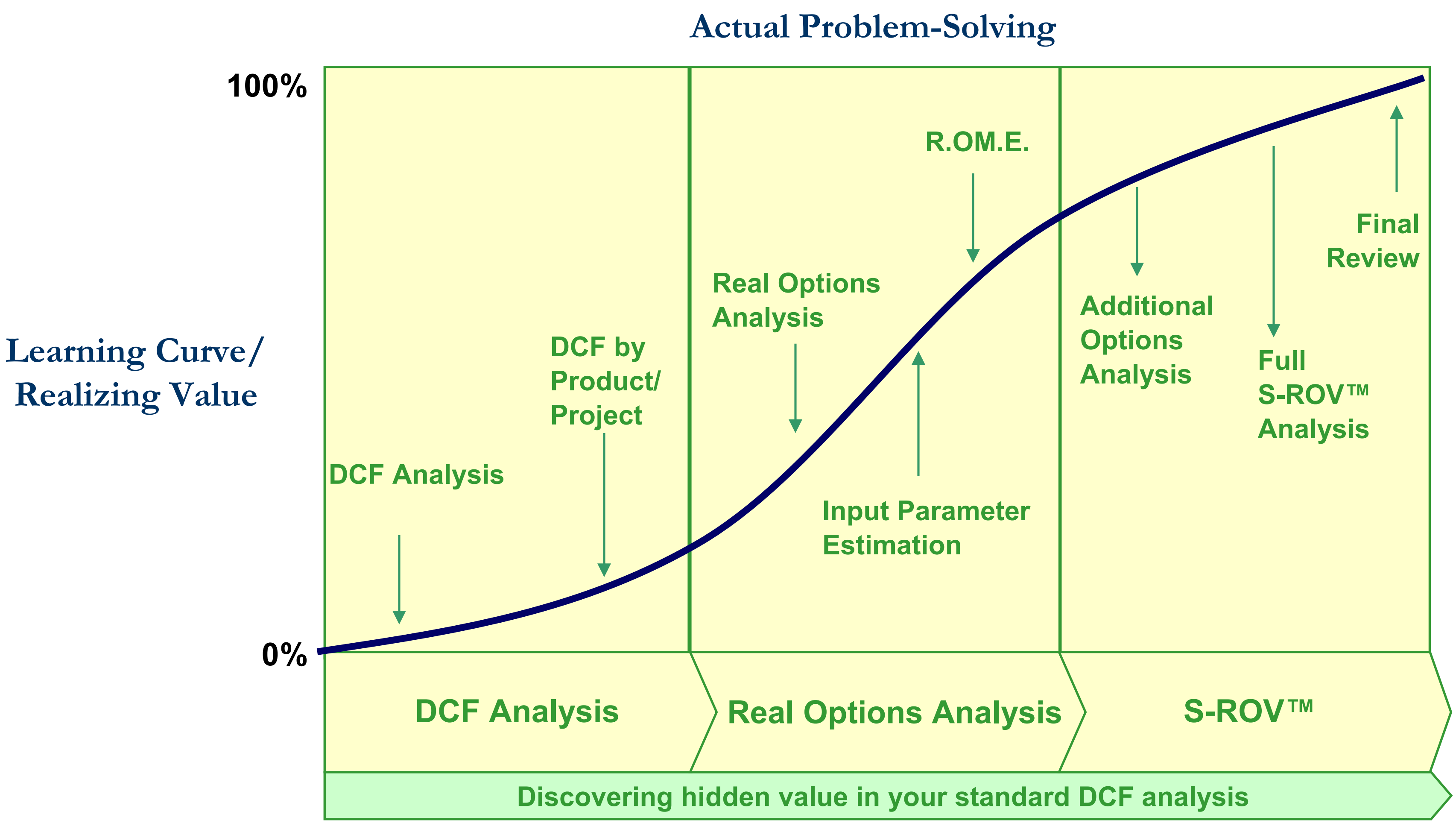
S-ROV™ Process*



Step 1

DCF per product

We have calculated the DCF value for each product (see appendix 1)
The results are :

Product	ROG DCF Value (€ '000)
Polyphenon	65,858
HPV vac	194,137
Etomoxir	17,937
G207	399,938
Mal Melanoma	118,940
NV 1020	22,545
ITD Platform	(423,294)
CF Adjustments (1)	443,839
Net Debt	(94,881)
Total Medigene	745,019

(1) The calculation includes 5 categories of adjustments described in Appendix 2

Step 2

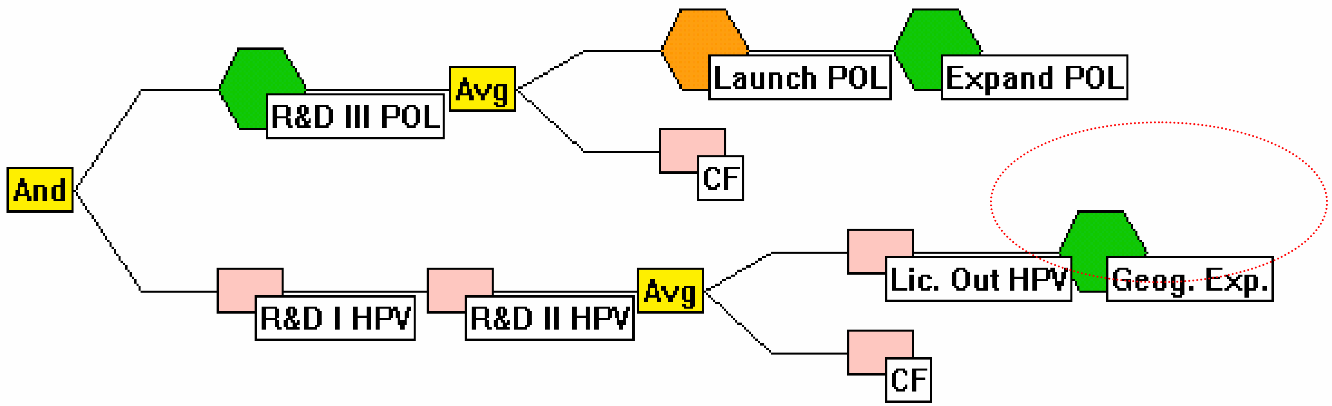
Identify Real Options

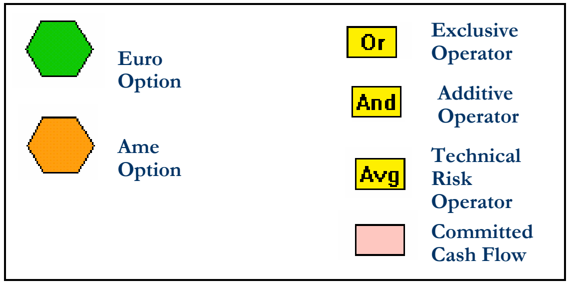
BY DEVELOPMENT STAGE

BY DESEASE AREA

	R&D Process Optimisation	Contractual Options	Expansion Options
Infection	▪ Stage R&D (and abandon) Polyphenon	▪ License out HPV to Schering	▪ Launch & expand Polyphenon
Cardiovascular	▪ Stage R&D (and abandon) Etomoxir		▪ Launch & expand Etomoxir
Oncology	▪ Stage R&D (and abandon) G207 ▪ Stage R&D (or abandon) NV1020	▪ License out rAVV to Aventis ▪ License out NV1020	▪ Launch & expand G207

Step 2 Option Map-Infection Group





Not included in the calculations

Step 2 Interactions-Infection Group

Option to Develop 3rd stage of clinical trials depends on follow-on option to launch and expand

There are states where project has negative NPV but is worth investing to capture value of option to launch and expand later

Not exercising the launch option kills option to expand later

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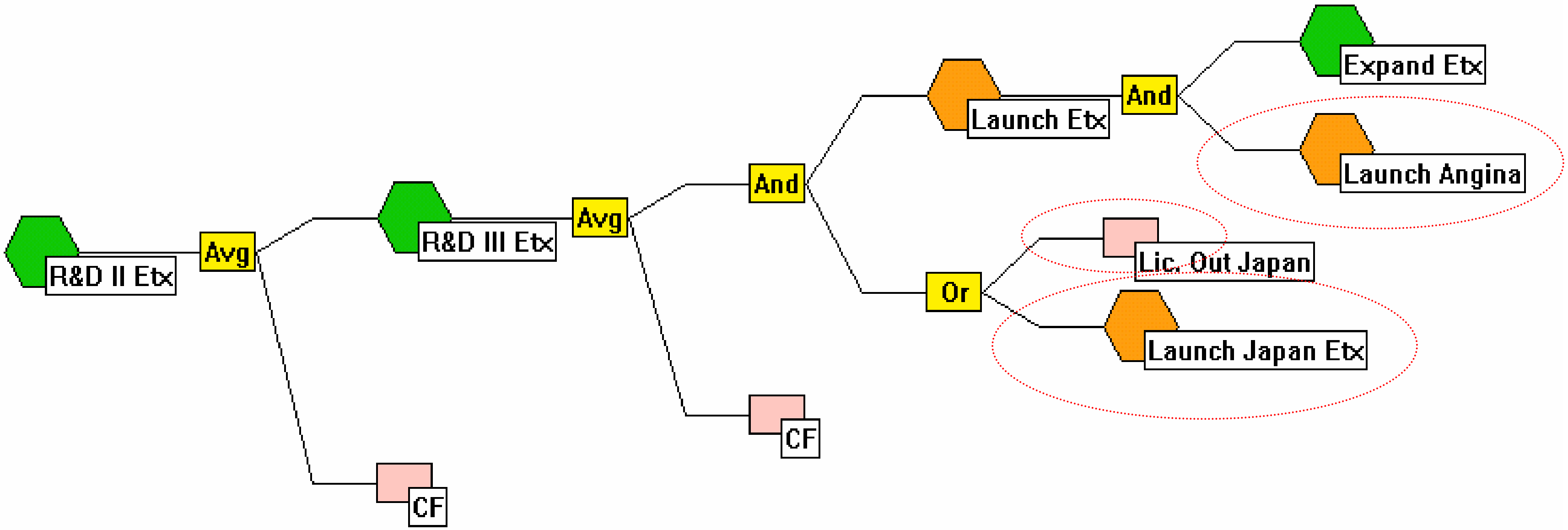
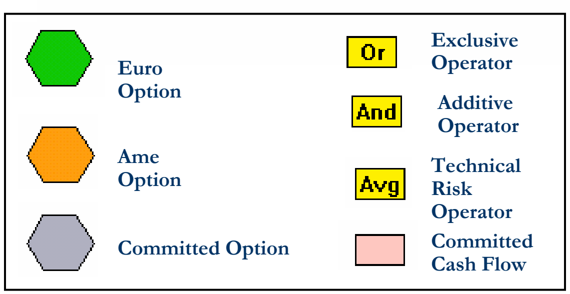
Step 2

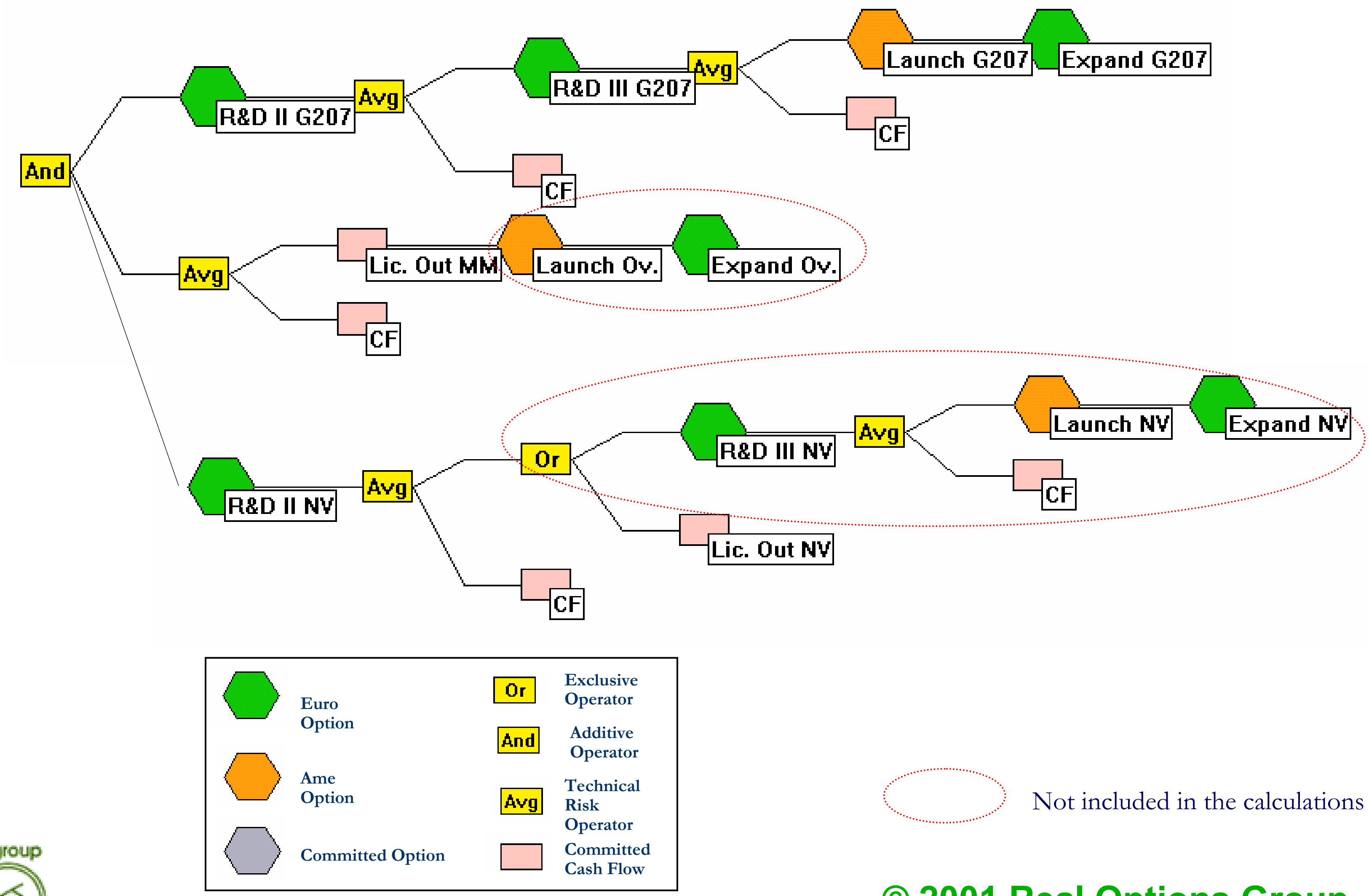
Option Map-Cardiovascular Group





Not included in the calculations

Step 2 Option Map-Oncology Group



Step 2

Interactions-Cardiovascular and Oncology Group

Option to Develop 2nd and 3rd stage of clinical trials depends on follow-on option to launch and expand

There are states where project has negative NPV but is worth investing to capture value of option to launch and expand later

Not exercising the launch option kills option to expand later

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Step 3

Identify Main Value Drivers

Main risk driver is demand uncertainty, both total market and market share.

Total market= addressable market* treatment price/patient

Step 3

Input Parameters - Infection Group

Polyphenon (€ '000)

Option parameters	R&D III	Launch Polyphenon		Expand Polyphenon	
Capital Investment	-11,715	-15,376		-50,941	
Time to Maturity (years)	2	2-5		6	
Type of option	European	American		European	
Underlying asset	Option to launch	Operating cash-flows from launching plus option to expand		Operating cash-flows from expanding	
		= Initial Value	65,697	= Initial Value	63,022
		Volatility	30%	Volatility	20%
		Growth rate	5%	Growth rate	4%
		Risk free rate	5.2%*	Risk free rate	5.2%

Step 3

Input Parameters - Infection Group

HPV: Committed decisions: Use DCF (€ '000)

Decision	Time	Amount
R&D I	0	3,509
R&D II	1	5,822
License out HPV	4	298,306

Step 3

Input Parameters - Cardiovascular Group

Etomoxir (€ '000)

Option parameters	R&D II	R&DIII	Launch Etomoxir		Expand Etomoxir	
Capital Investment	-8,564	-26,756	-68,376		-245,625	
Time to Maturity (years)	0	2	4-6		6	
Type of option	European	European	American		European	
Undelying asset	Option to complete R&D III	Option to launch	Operating cash-flows from launching plus option to expand		Operating cash-flows from expanding	
			= Initial Value	69,300	= Initial Value	204,718
			Volatility	30%	Volatility	20%
			Growth rate	3.7%	Growth rate	3.5%
			Risk free rate	5.2%	Risk free rate	5.2%

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Step 3

Input Parameters - Oncology Group

G207 (€ '000)

Option parameters	R&D II	R&DIII	Launch G207		Expand G207	
Capital Investment	-6,840	-37,710	-28,697		-122,818	
Time to Maturity (years)	0	2	4-6		7	
Type of option	European	European	American		European	
Undelying asset	Option to complete R&D III	Option to launch	Operating cash-flows from launching plus option to expand		Ooperating cash-flows from expanding	
			= Initial Value	196,578	= Initial Value	354,652
			Volatility	30%	Volatility	20%
			Growth rate	2%	Growth rate	1.5%
			Risk free rate	5.2%	Risk free rate	5.2%

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Step 3

Input Parameters - Oncology Group

Malignant Melanoma (€ '000)

Decision	Time	Amount
License out MM	0	118,940

NV 1020 (€ '000)

Option parameters	R&D II
Capital Investment	-28513
Time to Maturity (years)	2
Type of option	European
Underlying asset	The best of two assets: Complete R&D III or license out NV 1020

NV 1020: Committed decisions: Use DCF

Decision	Time	Amount
License out NV1020	3	67,102

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Step 3

Input Parameters - Technical Risk

This kind of uncertainty, different from economic uncertainty (i.e., demand), is endogenous to the project.

It is quantified through probabilities of success/failure within MediGene´s R&D process.

TECHNICAL RISK *

	STAGE OF CLINICAL TRIALS			
Group	**I**	**II**	**III**	**FDA**
Infection	60%	70%	85%	93%
Cardiovascular	45%	60%	80%	90%
Oncology	40%	55%	80%	92%

* ROG Estimates

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Step 5

Full S-ROV ™

By allowing for managerial flexibility, R.O.M.E allows to calculate Medigene's total Strategic Real Option Value (S-ROV) which fully incorporates the company's portfolio of Real Options

Results are shown according to whether decisions are committed or options

Committed Decisions Real Actual Probabilities
Non-Committed Decisions Real Actual Probabilities

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Step 5

Full S-ROV ™

		Committed decisions Real Prob.	Options Real Prob.
Infection	Polyphenon	17,464	30,045
	HPV	130,047	130,047
	Total Infection	147,511	160,092
Cardiovascular	Etoxomir	(40,199)	43,163
Oncology	G 207	123,503	198,560
	Mal. Melanoma	59,470	59,470
	NV 1020	3,021	3,021
	Total Oncology	185,994	261,051

ITD Platform	(423,294)	(423,294)
CF Adjustments	443,839	443,839
Net Debt	(94,881)	(94,881)
Total MediGene	313,851	484,851

ROV = 171,000

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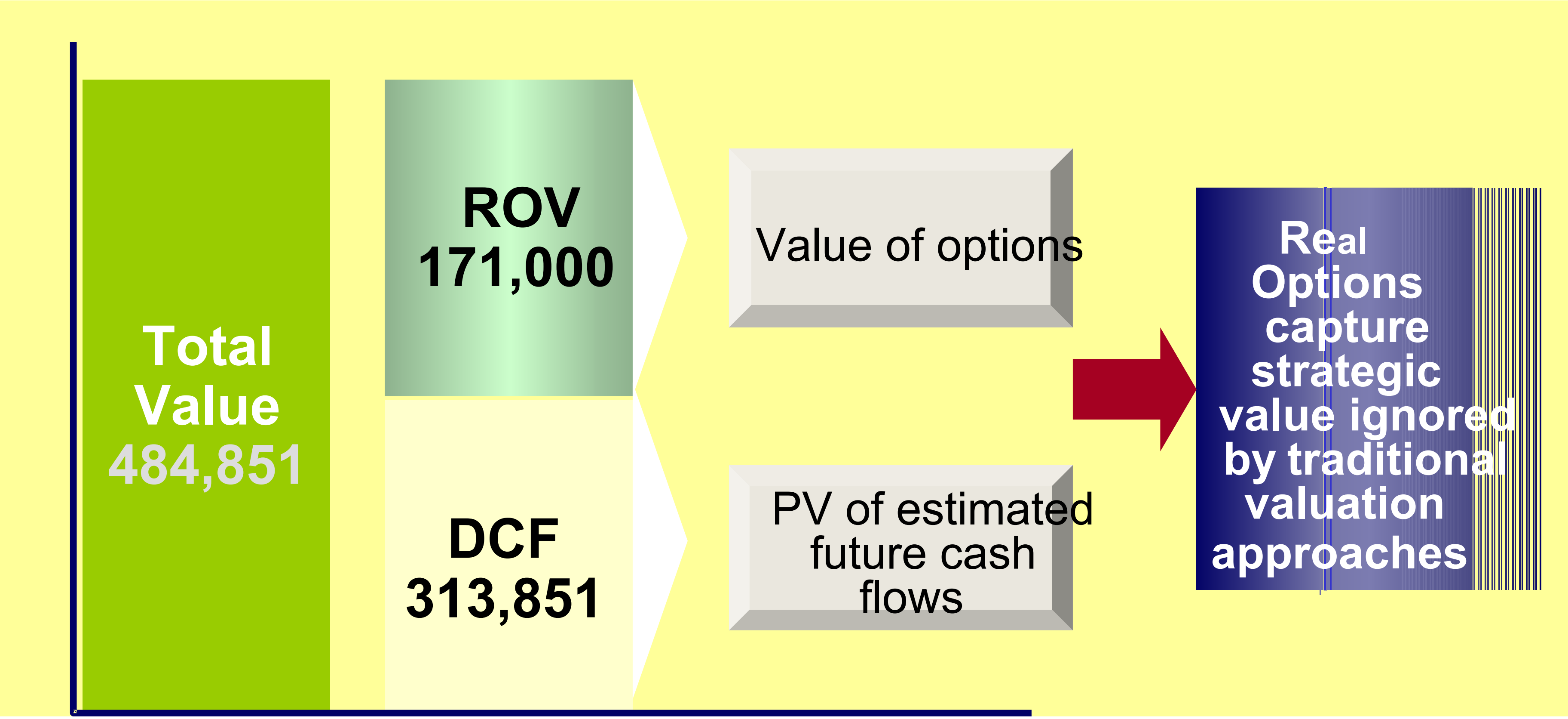
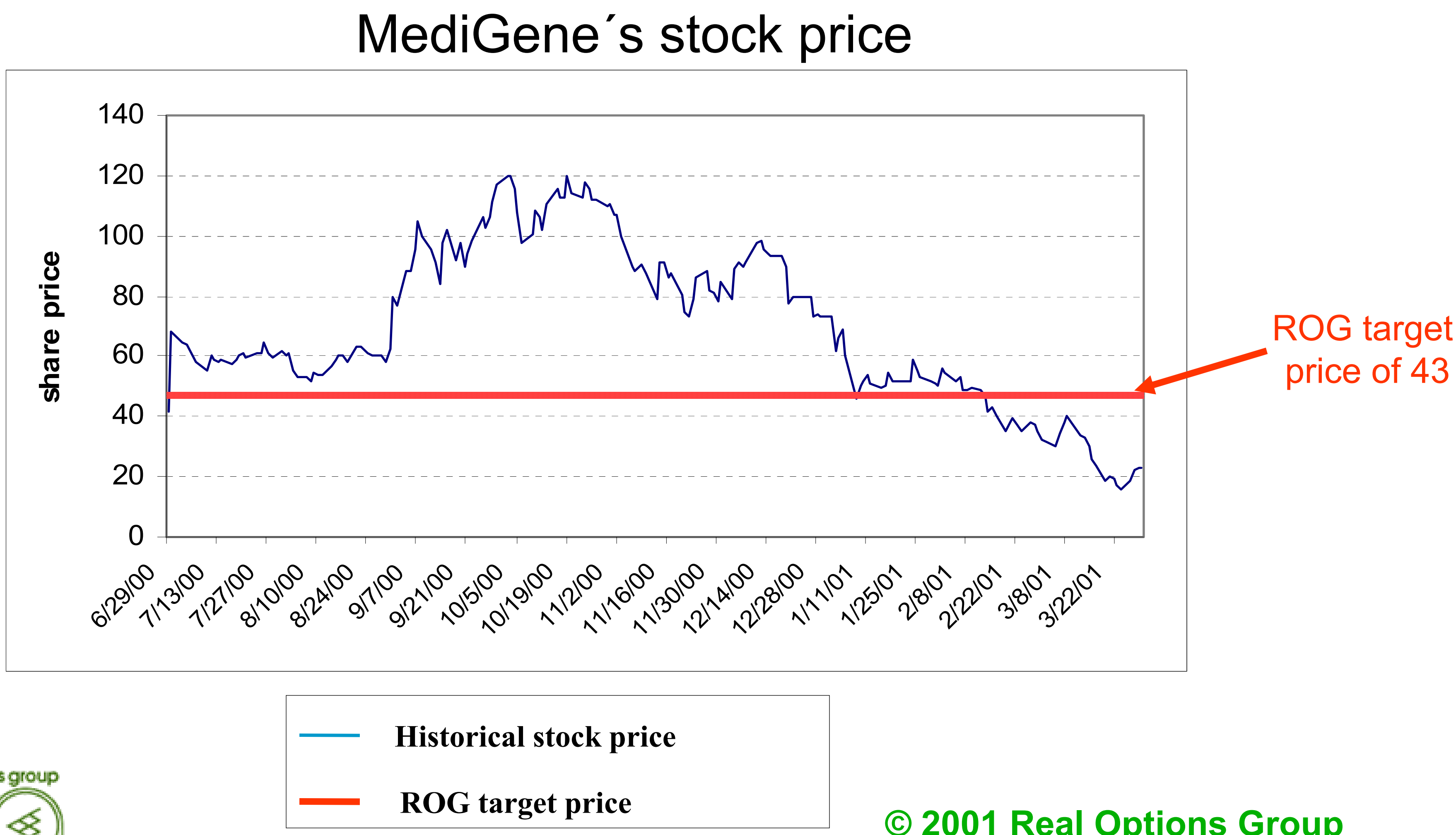
Results

Total Value Breakdown



Results



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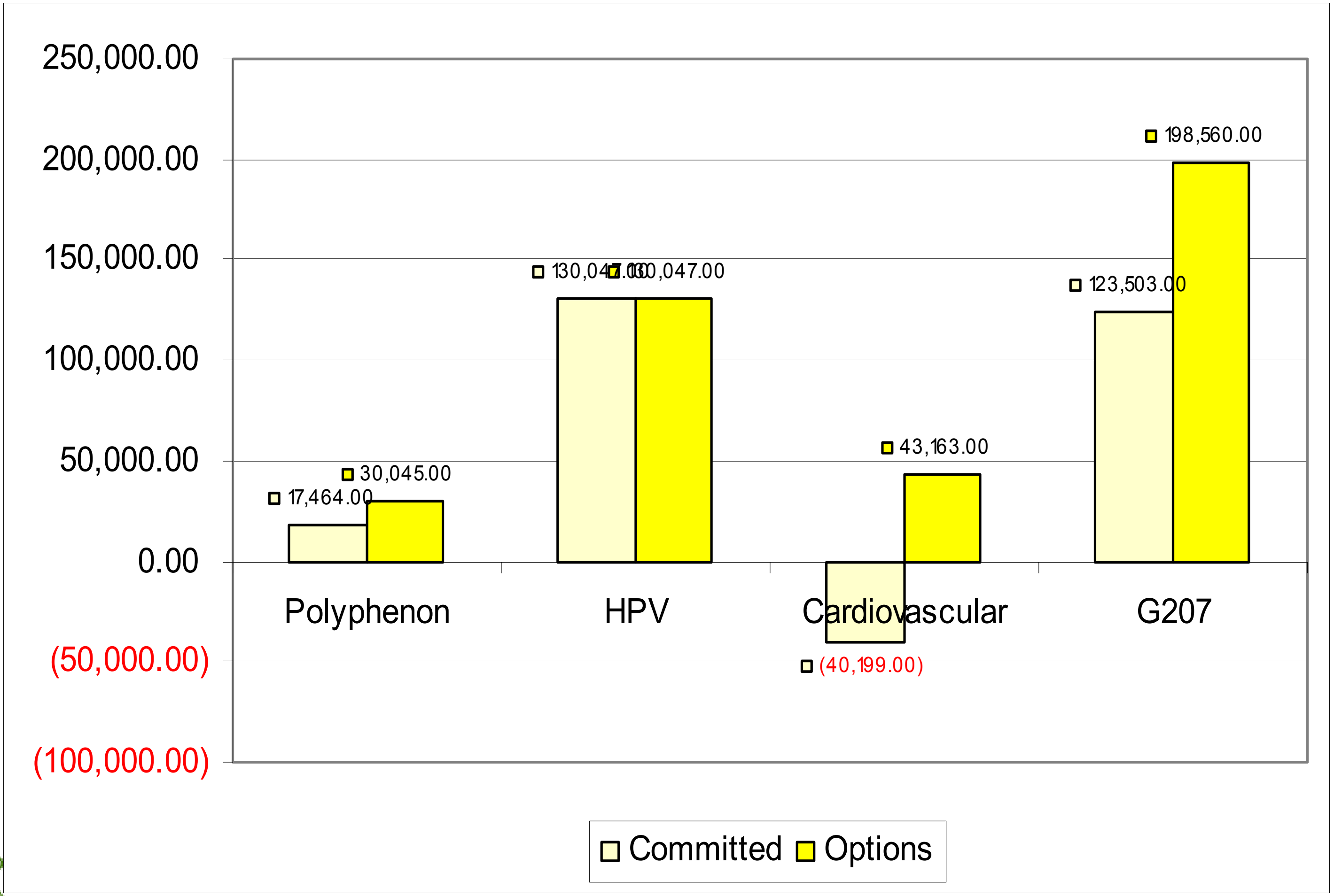
Results

Committed vs. Non-Committed (optional) Decisions



Robustness of Results

We believe that the final result is particularly robust due to four major reasons

We have implemented a valuation-by-components whereby each project/product was analysed in detail

We have taken into account the technical risk of failure during the R&D process

We have taken into account the market risk and the value of managerial flexibility

We have conducted a statistical analysis on a sample of comparables over a 10- year time horizon by considering Real Options driven variables such as R&D/Sales, Volatility and Skewness of stock returns and obtained consistent results (See PVGO Analysis)

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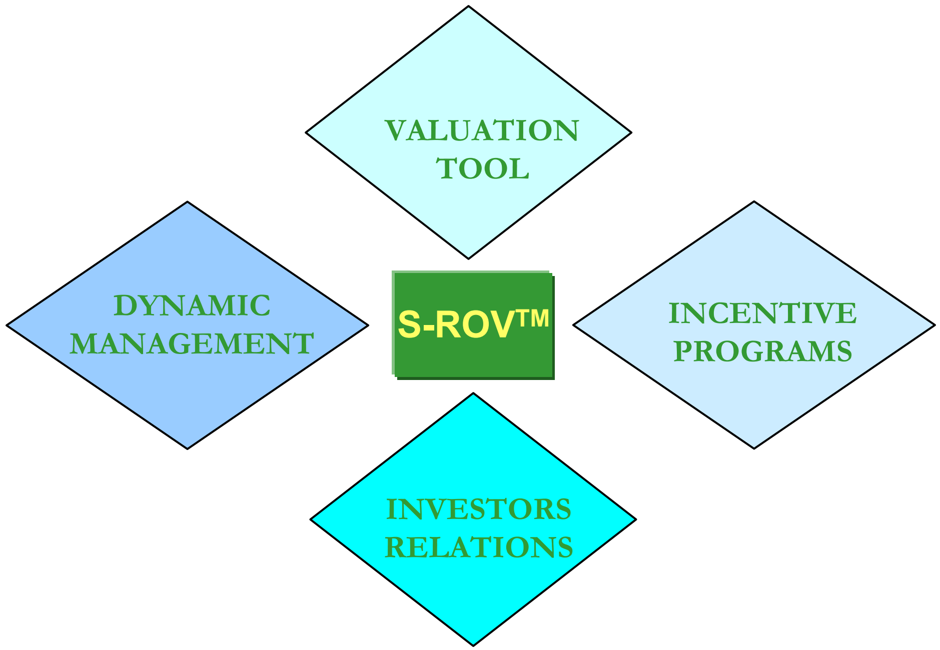
Applicability of Results

- Value-rationale of the sustainable target price
- Reference for mergers, acquisitions and strategic disposal of assets

- Optimisation of strategic plans and investment decisions



- Rewards based on the additional real option value created
- Alignment of management and shareholders interests

- Timing optimisation of communicating growth value to market investors
- Leads investors to better reflect growth potential in stock price

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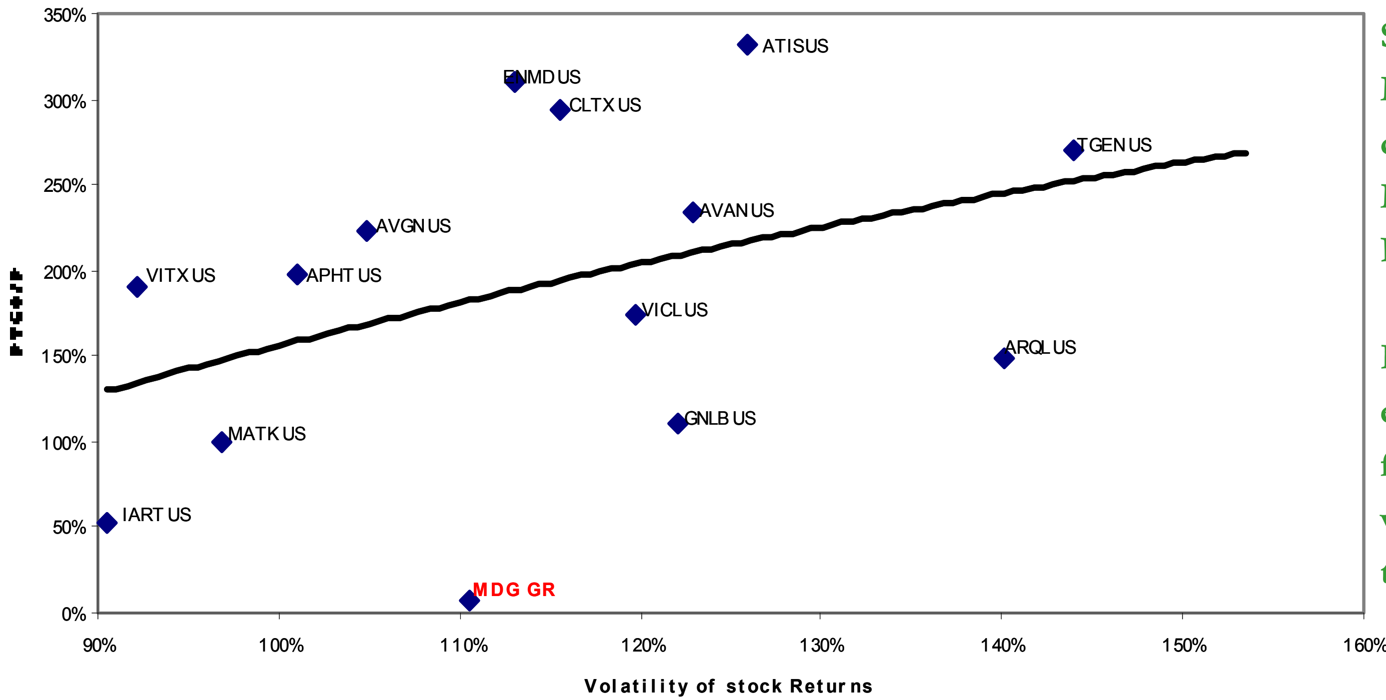
PVGO Analysis



S-ROV™ result for Medigene shows that at current market cap of 160 Mn, PVGO/P is negative (as PVGO = Mkt Cap – DCF)

If Mkt Cap were 392 Mn, even without considering further options, the PVGO/P would be more in line with the sector's standard

PVGO/P target level for Medigene

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PVGO Analysis

The PVGO curve is the result of a regression analysis conducted on a set of variables closely related to real options thinking that explain the growth options characteristics of stock prices. The regression is calculated on a ten year horizon by taking into account all companies belonging to the same industry (High Tech)

Each dot represents the actual PVGO against volatility of stock returns and is calculated as follows: (Spot price – (Exp(EPS)/(k-g))/Spot price

where k is the opportunity cost of capital and g is the expected growth rate of EPS

All companies situated below the curve are considered to be undervalued, vice versa all companies situated above the curve are considered to be overvalued

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Appendix

DCF by Product

DCF Adjustments

Sensitivity Analysis

Appendix 1: DCF by product

DCF of Polyphenon

Cash Flow STMT. ('000 €)	2001E	2002E	2003E	2004E	2005E	2006E	2007E	2008E	2009E	2010E
Market Sales	49.000	51.512	54.153	56.930	59.849	62.917	66.143	69.534	73.099	76.847
WorldwideMarket Share	2,0%	3,0%	7,0%	15,0%	30,0%	40,0%	50,0%	60,0%	70,0%	80,0%
Total Revenues (€ '000)	**0**	**0**	**3.791**	**8.539**	**17.955**	**25.167**	**33.072**	**41.721**	**51.170**	**61.478**
EBIT	**0**	**0**	**3.079**	**6.947**	**14.626**	**20.527**	**27.009**	**34.114**	**41.890**	**50.387**
- Tax paid (1)	0	0	-1.078	-2.431	-5.119	-7.185	-9.453	-11.940	-14.661	-17.635
Cash Flows from Operations	990	510	-156	2.949	7.443	14.063	17.753	21.846	27.003	32.626
Total Capex	**-4.500**	**-6.000**	**-3.702**	**-2.553**	**-5.360**	**-7.505**	**-9.850**	**-12.411**	**-15.203**	**-18.244**
Net Cash Flow	**-3.510**	**-5.490**	**-3.858**	**396**	**2.082**	**6.558**	**7.904**	**9.436**	**11.800**	**14.383**

Value of the Project	65.858

(1) Tax paid is not consistent with total company DCF since R&D costs and Sales and Mktg costs are left apart

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Appendix 1: DCF by product

DCF of Etoxomir

Cash Flow STMT. ('000 €)	2001E	2002E	2003E	2004E	2005E	2006E	2007E	2008E	2009E	2010E
US Market Sales (€ '000)	1.914.538	1.986.908	2.062.013	2.139.957	2.220.848	2.304.796	2.391.917	2.482.331	2.576.163	2.673.542
EU Market Sales (€ '000)	1.065.556	1.102.780	1.141.306	1.181.177	1.222.441	1.265.146	1.309.344	1.355.085	1.402.425	1.451.418
Market Share US	0,48%	0,66%	0,90%	1,24%	1,70%	2,33%	3,19%	4,38%	6,01%	8,24%
Market Share Europe	0,42%	0,58%	0,79%	1,09%	1,50%	2,07%	2,84%	3,91%	5,38%	7,40%
Total Revenues	**0**	**0**	**0**	**0**	**0**	**79.845**	**113.652**	**161.772**	**230.266**	**327.761**
EBIT	**0**	**0**	**0**	**0**	**0**	**53.149**	**75.769**	**108.012**	**153.968**	**219.466**
- Tax paid (1)	0	0	0	0	0	-18.602	-26.519	-37.804	-53.889	-76.813
Cash Flows from Operations	**990**	**135**	**1.875**	**-200**	**-1.000**	**16.893**	**46.748**	**64.575**	**93.161**	**134.218**
Total Capex	**-4.500**	**-4.500**	**-12.500**	**-10.000**	**-6.000**	**-27.389**	**-43.175**	**-62.536**	**-85.683**	**-112.900**
Net Cash Flow	**-3.510**	**-4.365**	**-10.625**	**-10.200**	**-7.000**	**-10.496**	**3.573**	**2.040**	**7.478**	**21.318**

Value of the Project	**17.937**

(1) Tax paid is not consistent with total company DCF since R&D costs and Sales and Mktg costs are left apart

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Appendix 1: DCF by product

DCF of G207

Cash Flow STMT. (' 000 €)	2001E	2002E	2003E	2004E	2005E	2006E	2007E	2008E	2009E	2010E
Worldwide Market Sales (€ '000)	462.400	471.741	481.271	490.993	500.912	511.031	521.355	531.887	542.631	553.593
Market Share	2,0%	2,9%	4,1%	5,9%	8,4%	12,0%	17,2%	24,7%	35,3%	50,6%
Total Revenues	**0**	**0**	**0**	**0**	**42.111**	**61.516**	**89.861**	**131.268**	**191.755**	**280.114**
EBIT	**0**	**0**	**0**	**0**	**32.198**	**47.099**	**68.895**	**100.772**	**147.393**	**215.573**
- Tax paid (1)	0	0	0	0	11.269	16.485	24.113	35.270	51.587	75.451
Cash Flows from Operations	**1.540**	**1.710**	**-130**	**-320**	**11.916**	**29.677**	**42.845**	**62.085**	**92.024**	**135.787**
Total Capex	**-7.000**	**-13.000**	**-13.000**	**-10.000**	**-6.201**	**-9.189**	**-20.830**	**-31.869**	**-43.342**	**-55.261**
Net Cash Flow	**-5.460**	**-11.290**	**-13.130**	**-10.320**	**5.715**	**20.488**	**22.016**	**30.216**	**48.682**	**80.526**

Value of the Project	**399.938**

(1) Tax paid is not consistent with total company DCF since R&D costs and Sales and Mktg costs are left apart

Appendix 1: DCF by product

DCF of Mal Melanoma

Cash Flows (€'000)	2001E	2002E	2003E	2004E	2005E	2006E	2007E	2008E	2009E	2010E
Total Market (€'000)	2,860,209.42	2,917,989.48	2,976,936.78	3,037,074.89	3,098,427.87	3,161,020.27	3,224,877.11	3,290,023.95	3,356,486.84	3,424,292.38
Market share	0.02%	0.03%	0.04%	0.11%	0.30%	0.78%	2.00%	5.00%	7.50%	10.00%
Total Revenues	2,293	2,467	5,660	4,425	2,774	2,676	10,319	16,450	25,174	34,243
EBIT	2,201	2,371	5,447	4,263	2,676	2,584	9,975	15,918	24,384	33,202
Tax paid	(770)	(830)	(1,906)	(1,492)	(937)	(904)	(3,491)	(5,571)	(8,535)	(11,621)
Cash Flows from Operations	1,875	1,530	2,927	3,337	2,183	1,256	6,092	10,235	15,723	21,670
Total Capex	(4,000)	(3,250)	(3,000)	(3,000)	(2,500)	0	0	0	0	0
Net Cashflows	(2,125)	(1,720)	(73)	337	(317)	1,256	6,092	10,235	15,723	21,670

Value of the Project	118,940

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Appendix 1: DCF by product

DCF of NV1020

Cash Flow STMT. (' 000 €)	2001E	2002E	2003E	2004E	2005E	2006E	2007E	2008E	2009E	2010E
Worldwide Market Sales (€ '000)	1.618.400	1.651.094	1.684.448	1.718.476	1.753.192	1.788.609	1.824.741	1.861.603	1.899.210	1.937.577
Market Share	0,40%	0,60%	0,90%	1,30%	1,50%	2,00%	4,00%	6,00%	7,50%	9,00%
Total Revenues	0	0	0	10.000	5.000	7.846	3.962	5.517	7.681	10.695
EBIT	0	0	0	9.635	4.823	7.576	3.830	5.338	7.441	10.370
- Tax paid (1)	0	0	0	3.372	1.688	2.652	1.341	1.868	2.604	3.629
Cash Flows from Operations	1.320	1.180	380	1.448	4.562	5.224	3.226	3.485	4.850	6.749
Total Capex	-6.000	-10.000	-12.000	0	0	0	0	0	0	0
Net Cash Flow	-4.680	-8.820	-11.620	1.448	4.562	5.224	3.226	3.485	4.850	6.749

Value of the Project	22.545

(1) Tax paid is not consistent with total company DCF since R&D costs and Sales and Mktg costs are left apart

Appendix 1: DCF by product

DCF of ITD Platform

Cash Flow STMT. (' 000 €)	2001E	2002E	2003E	2004E	2005E	2006E	2007E	2008E	2009E	2010E
Number of Deals	1	0	1	0	1	0	0	0	0	0
Total Revenues	4.590	7.113	12.098	13.121	14.654	14.654	10.703	12.782	9.433	17.512
EBIT	4.407	6.837	11.643	12.642	14.136	14.151	10.347	12.369	9.138	16.979
- Tax paid (1)	-1.542	-2.393	-4.075	-4.425	-4.947	-4.953	-3.621	-4.329	-3.198	-5.943
Cash Flows from Operations	3.092	4.790	7.046	9.901	11.687	14.474	10.863	11.235	9.587	13.721
Total Capex	-5.000	-7.000	-8.000	-12.000	-18.000	-30.000	-40.000	-50.000	-60.000	-70.000
Net Cash Flow	-1.908	-2.210	-954	-2.099	-6.313	-15.526	-29.137	-38.765	-50.413	-56.279

Value of the Project	-423.294

(1) Tax paid is not consistent with total company DCF since R&D costs and Sales and Mktg costs are left apart

Appendix 2:DCF Adjustments

Capex Tax Credit

Capex Discount Rate

Selling, General and Administration Costs

Working Capital

General Infrastructure Capex

Appendix 3:Sensitivity analysis

	Volatility		Initial value of Underlying	
	Δ10%	∇10%	Δ10%	∇10%
Infection	161,727	159,269	166,270	154,032
	1,02%	0,51%	3,9%	3,8%
Cardiovascular	64,340	22,776	63,174	25,588
	49%	47%	46%	40%
Oncology G207	199,473	198470	226,088	171,049
	0,5%	0,05%	14%	14%