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Creating Value Through Flexibility!

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gsk GlaxoSmithKline

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Valuation of Pharma R&D /Patent Rights

(Flexibility to Abandon Drug Development and Expand the Market)

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Three-step Real Options Valuation Process

Introduction

- I. Problem Structuring
- II. Evaluation
- III. Action Plan

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Introduction

- The Problem
- Background
- Project Milestones
- Management Strategy/Concerns
- Main Alternatives

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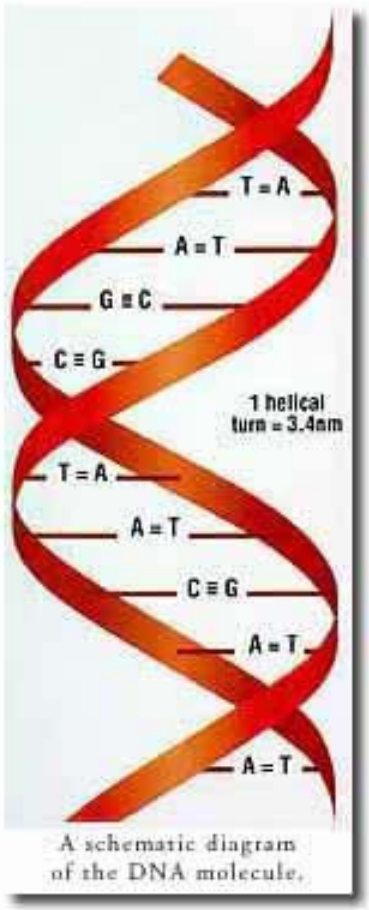
The Problem



A schematic diagram of the DNA molecule.

- Evaluate R&D investment (or patent rights) for a pharma drug (solving formation of antibacterial resistance that reduces efficacy of cures from long-term treatment)

Purpose:

- ➔ Value opportunity to invest in last stage of clinical trials
- ➔ Understand interactions among options to abandon development and expand the market

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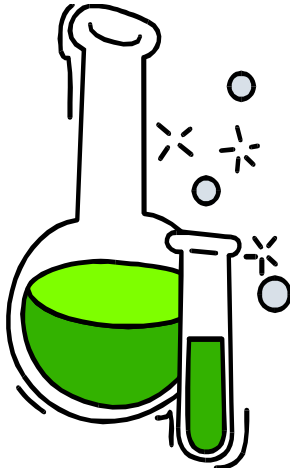
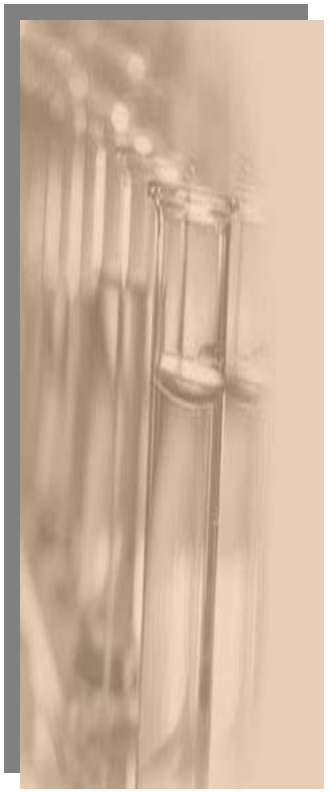
Background: The Company and its Strategy



- Glaxo is a pharmaceutical firm aimed to be world-wide leader in the research, development and marketing of drugs for human consumption
- Since 1980, Glaxo concentrated its activities on prescription drugs, focusing its skills & resources on the development of safer and more effective drugs
- An area of focus where Glaxo can have competitive advantage is antibiotics

Background: List of Products



LAUNCH DATE	DRUG	THERAPEUTIC CLASS
1993	Flixotide	Respiratory
1993	Zofran	Antiemetic
1991	Imigran	Antimigraine
1991	Lacipil	Antihypertensive
1991	Cutuvate	Dermatological
1990	Serevent	Respiratory
1990	Flixonase	Antirhinitic
1987	Zinnat	Oral antibiotic
1987	Volmax	Respiratory
1983	Fortum	Injectable antibiotic
1981	Zantac	Antiulcerant
1978	Zinacef	Injectable antibiotic
1977	Trandate	Antihypertensive
1975	Beconase	Antirhinitic
1973	Dermovate	Dermatological
1972	Becotide	Respiratory
1969	Ventolin	Respiratory
1964	Betnovate	Dermatological

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Background : Therapeutic Problem

- Shortly after starting antibiotics in therapy, bacteria mutate faster producing enzymes that inactivate the drug reducing its therapeutic value ("b-lactamase" process)
- Glaxo's research labs isolated a new synthetic compound (Tribactam) to prevent this effect
- The development enhances Glaxo´s strategy to be a leader in antibiotics

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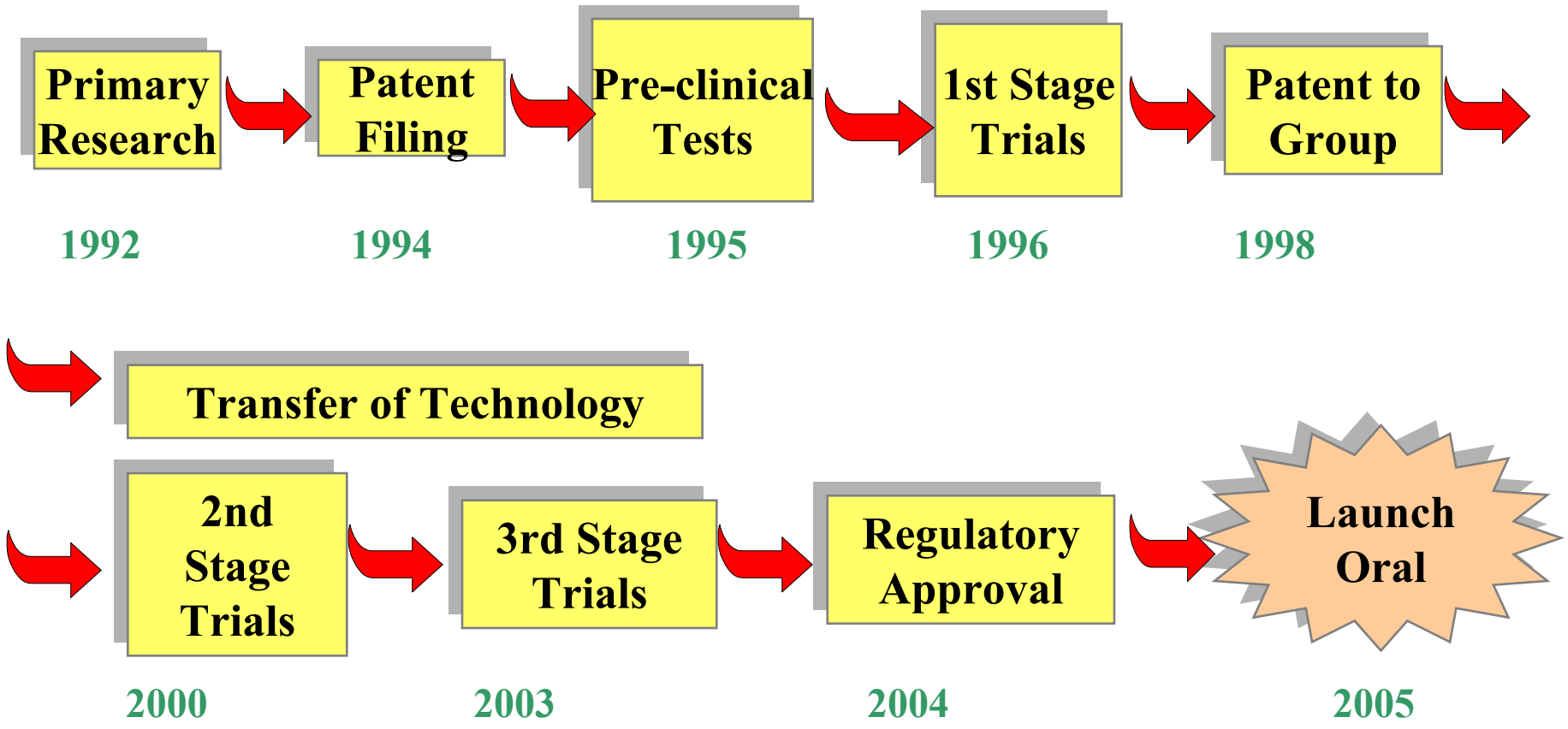
Project Milestones



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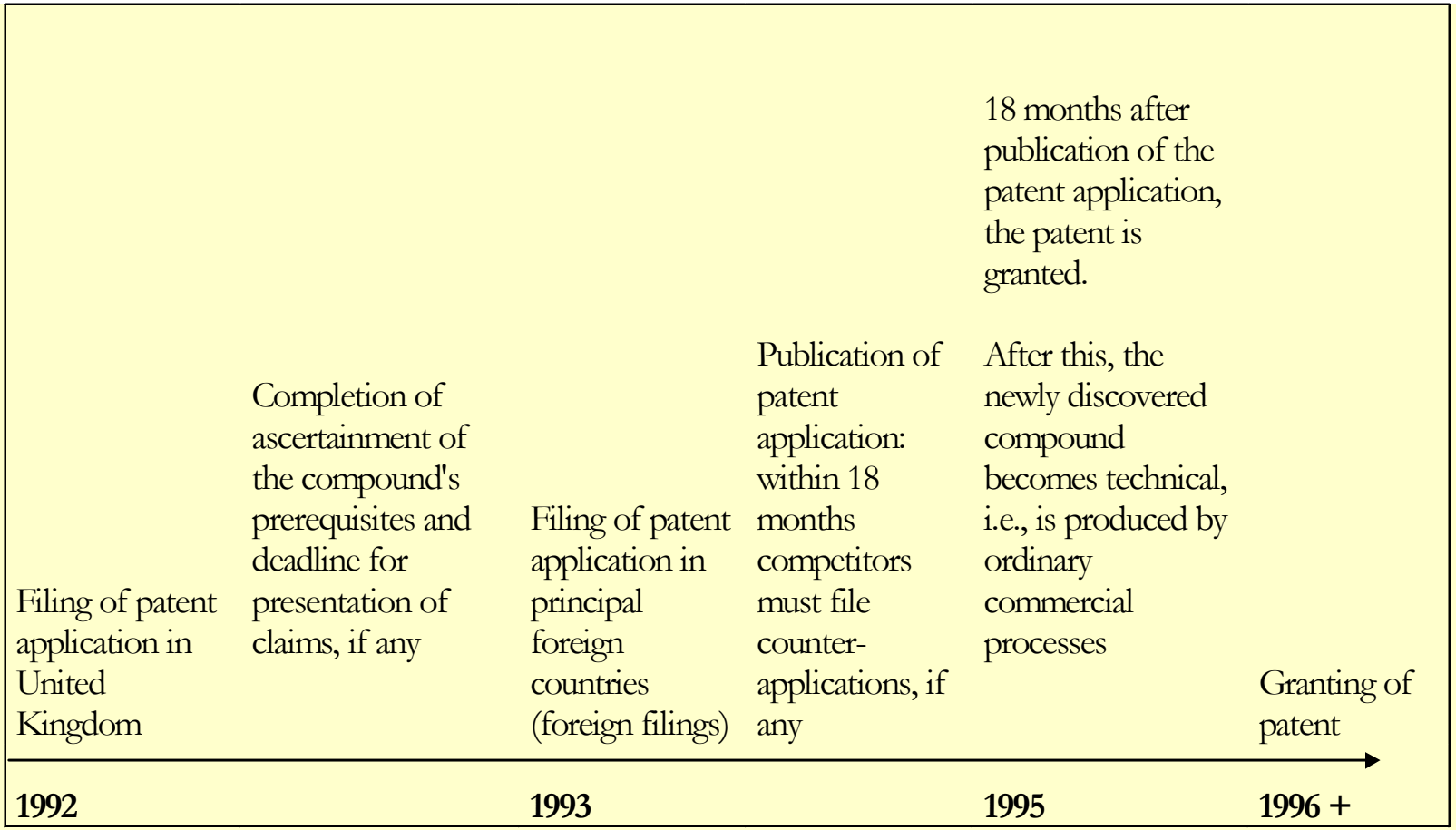
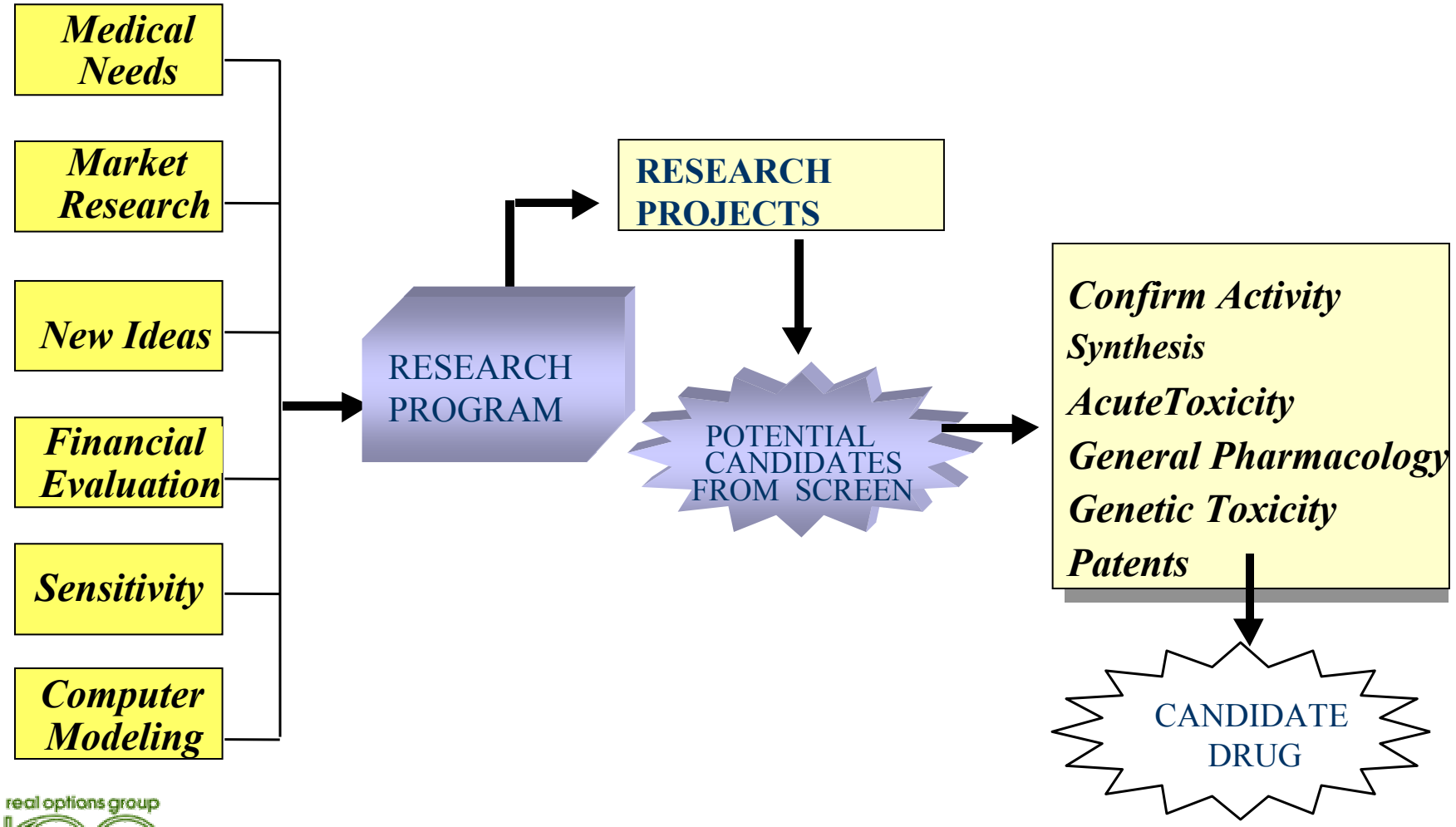
The Patent Process



Project Milestones (A): Primary Research Stage



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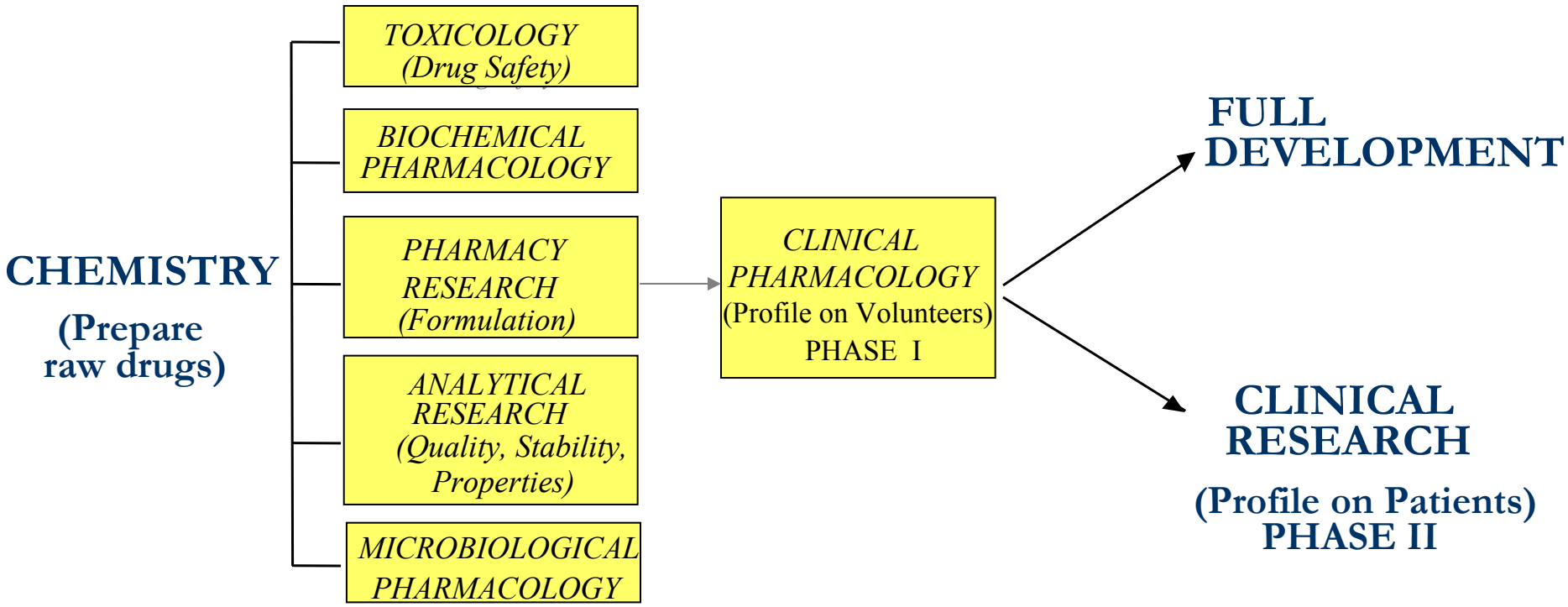
Project Milestones (B): Exploratoty Development Stage



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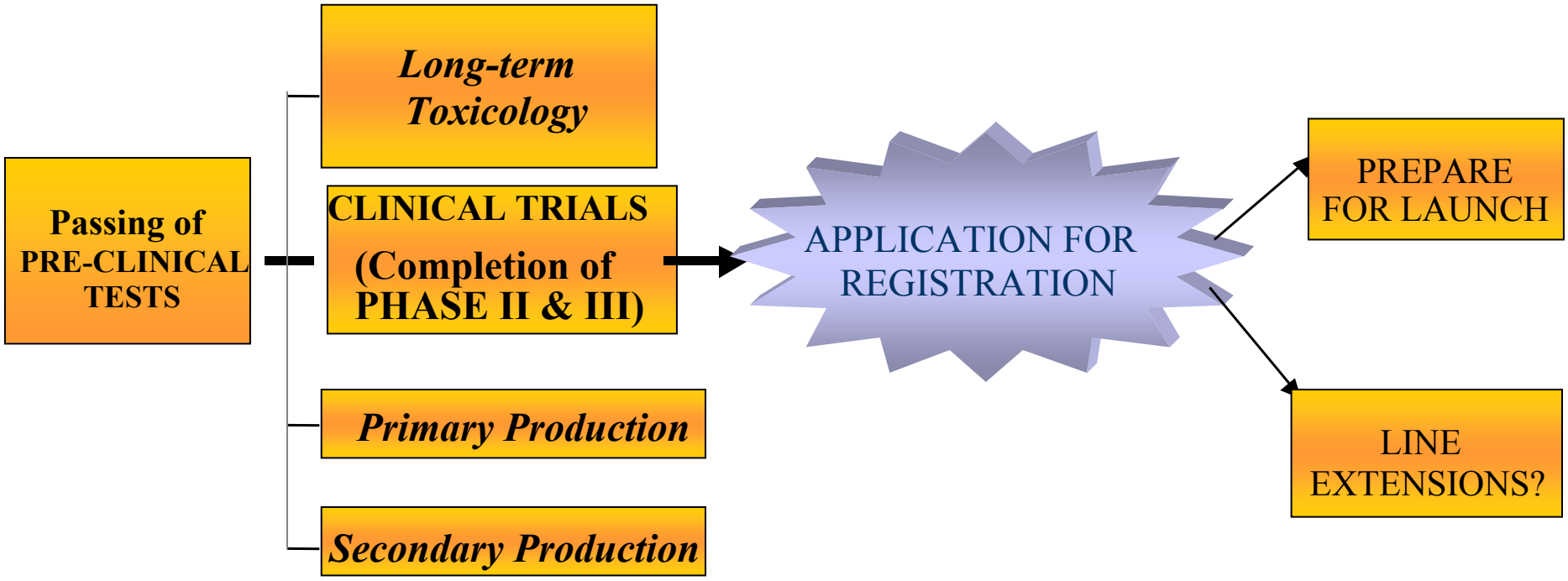
Project Milestones (C): Full Development Stage



Management Comments/Concerns

- **CEO :** *"We are faced with fundamental questions which affect the whole project's structure. For instance, we have not yet solved the issue of the timing and sequence of launches"*
- **Finance Director:** *"I often find myself having to make conditioned forecasts. For example, if the drug were also developed in an injectable dosage form, we could exploit the hospital channel as well, thus expanding our target market. As you can imagine, the project's value would increase enormously! So, which evaluation should I submit to our friends in London?"*

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Management Comments/Concerns

- **CEO :** *"I think that optimizing the project value along the way is one of our most critical tasks. For example, the ability to postpone injectable form puts a tremendous source of flexibility in our hands!"*
- **Project Manager:** *"What we need is to account for flexibility! It is simplistic to reduce a project with a complex, uncertain and contingent structure to a series of annual cash flow estimates"*
- **CEO :** *"So, in the end, is there any way to see part of the uncertainty in a favorable light?"*

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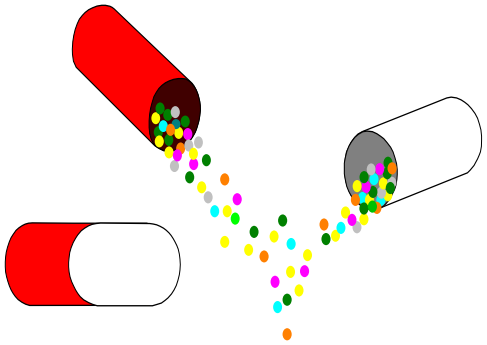
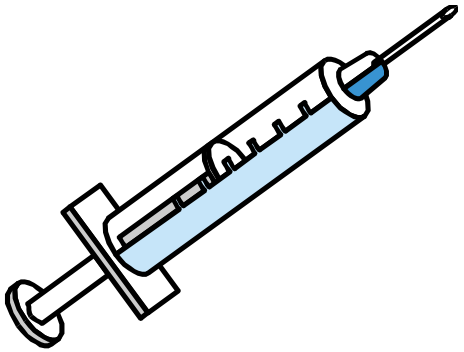
Main Alternatives: Marketing Strategy





- Launch both oral (solid) and injectable version at same time (2005)
- Launch injectable version one year later (2006). Less risk since oral has wider market use; more informed expansion into injectable (hospital)

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Phase I. Problem Structuring

- Main Value Drivers
- Project Timeline
- Specifying Options
- Option Interaction

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I. Identify Main Value Drivers

- Main risk driver is demand uncertainty (units sold) of oral (solid) version

(V =PV cash inflows from oral launch)

- But management intervention/optionality to reduce downside risk and expand upside

↘Option to abandon (put) during 3rd stage (or sell rights to biotech firm)

↗ Option to expand (call) into hospital market (launch injectable version) within a year following successful launch of oral version

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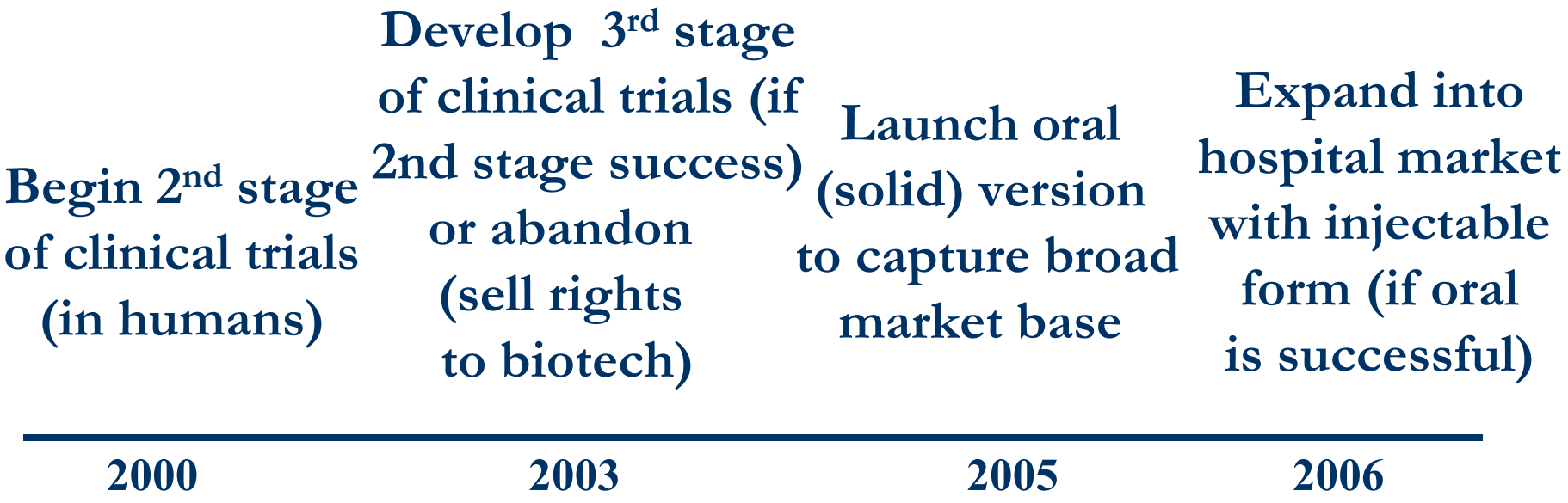
I. Project Timeline (Milestones)



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I. Glaxo´s Decision Map

DEVELOPMENT PHASE

COMMERCIAL PHASE (Life = 6 years)

EXPAND (INJECTABLE) Ie = 32

Technical uncertainty

Market demand uncertainty

BEGIN 2nd STAGE I_2 = 7.8

DEVELOP 3rd STAGE I_3 = 63.1

LAUNCH ORAL

e = 0.6

Max(R-I_3, S)

Max (eV-Ie, 0)

S = 5

ABANDON (SELL)

0 2000

3 2003

5 2005

6 2006

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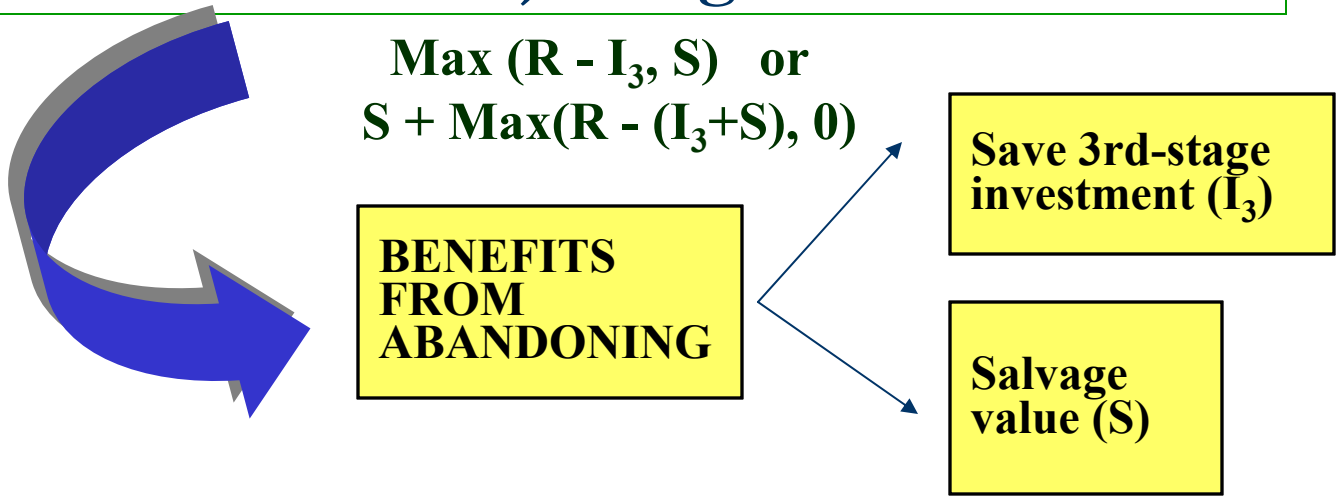
I. Specifying Options: Option to Abandon

- In 2000 project can be abandoned during development if PV from continuing (R) is less than planned (3rd-stage) investment (I_3) or if salvage value (S) (e.g., from selling rights to biotech firm) is higher



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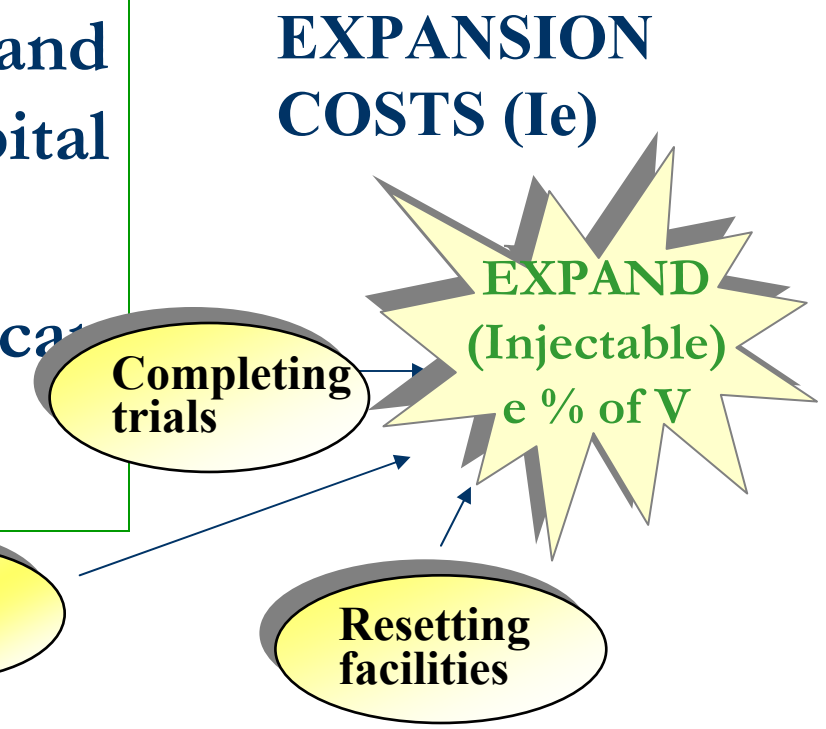
I. Specifying Options: Option to Expand

- Success of oral (solid) version would enhance company image as leader in this antibiotics field and leverage expansion into hospital market (with injectable version)
- By investing extra costs (Ie) ca… expand (into hospitals) by e%

$$R = V + \text{Max}(eV - Ie, 0)$$



I. Option Interactions

- Option to abandon planned 3rd stage development (or sell for salvage value) depends on follow-on option to expand (injectable)

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

- Exercising abandonment kills option to expand later

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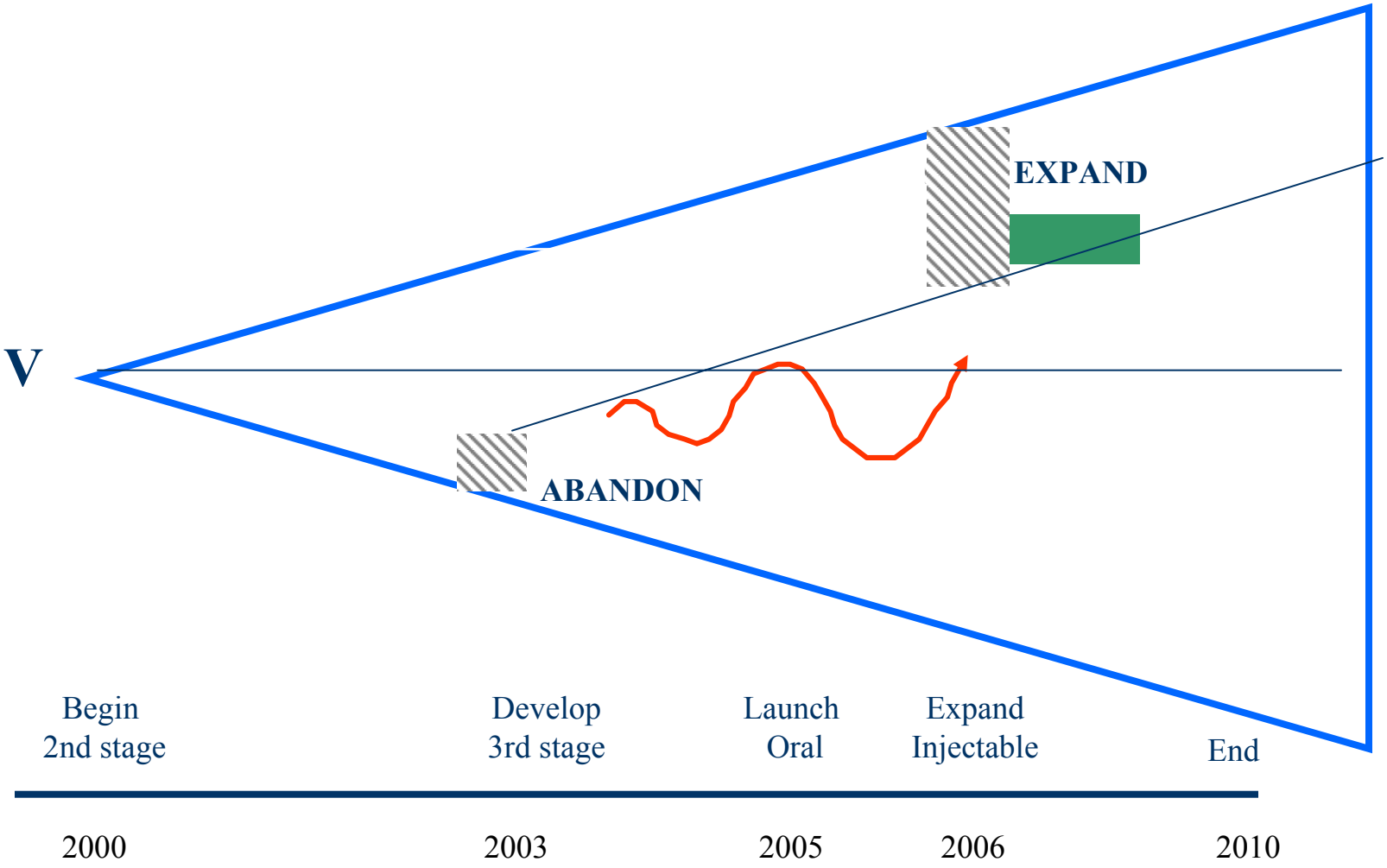
I. Option Interactions



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Phase II. Evaluation

- DCF Analysis
- Option Inputs
- Results
- Sensitivity
- Value Breakdown

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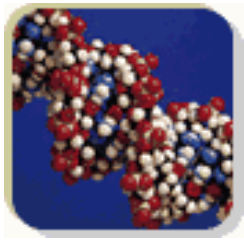
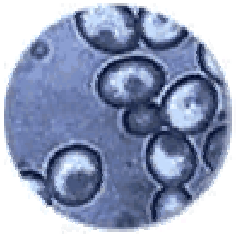
II. Primary Input Data (DCF) Estimates: Oral Version (Base-case)





- Unit price (P) = £1.90 until 2008, £2.00 after
- Project life (T) = 6 years (withdrawn 2011)
- COGS = 35% of Revenues
- Tax rate = 33% (of EBIT)
- WACC = 12%
- Depreciation: straight-line (£1.7 m /year)
- PV of capital expenditures (I_0) = £65.5 m, broken down as:
  - £7.8 m (2nd stage) in 2000
  - £63.1 m (3rd stage) in 2003

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II. DCF (NPV) Analysis

Base-case: NPV = -2.7 **Reject?**

Valuation Results

	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
REVENUES						95	184	209	219	260	260	
-COGS						22	58	74	81	86	90	
- MARKETING AND DISTRIB.						95	138	105	55	65	65	
- DEPRECIATION						1,7	1,7	1,7	1,7	1,7	1,7	
EBIT						-23,7	-13,6	28,8	81,2	107	103,3	
-TAXES						-8,5	-5,8	7,7	24,1	32,3	30,3	
PROFIT AFTER TAX						-15	-8	21	57	75	73	
DEPRECIATION						1,7	1,7	1,7	1,7	1,7	1,7	
CHANGE IN NET WORK. CAP.						19,5	20,9	6,8	2,7	7,8	0,7	-58,3
CASH FLOW FROM OPERAT.	0	0	0	0	0	-33,0	-27,0	16,0	56,0	69,0	74,0	58,3
Present Value of cash inflows (V)	**62,9**											
R&D												
R&D COST	-0,6	-0,6	-0,6	-2,5	-2,0	-1,5						
GRD STAFF	-0,2	-0,3	-0,4	-2,0	-1,0	-0,5						
TRIALS	0,0	-0,6	-1,0	-5,0	-3,5							
GLAXOCHEM	-0,8	-0,8	-0,1									
PRODUCTION INVESTM.												
PRIMARY PRODUCTION		-2,0										
SECONDARY PRODUCTION				-12,0	-15,0	-20,0						
CAPITAL EXPENDITURES	-1,6	-4,3	-2,1	-21,5	-21,5	-22,0						
Present Value of costs (I_0)	**-65,5**											
NPV = V-I_0	**-2,6**											

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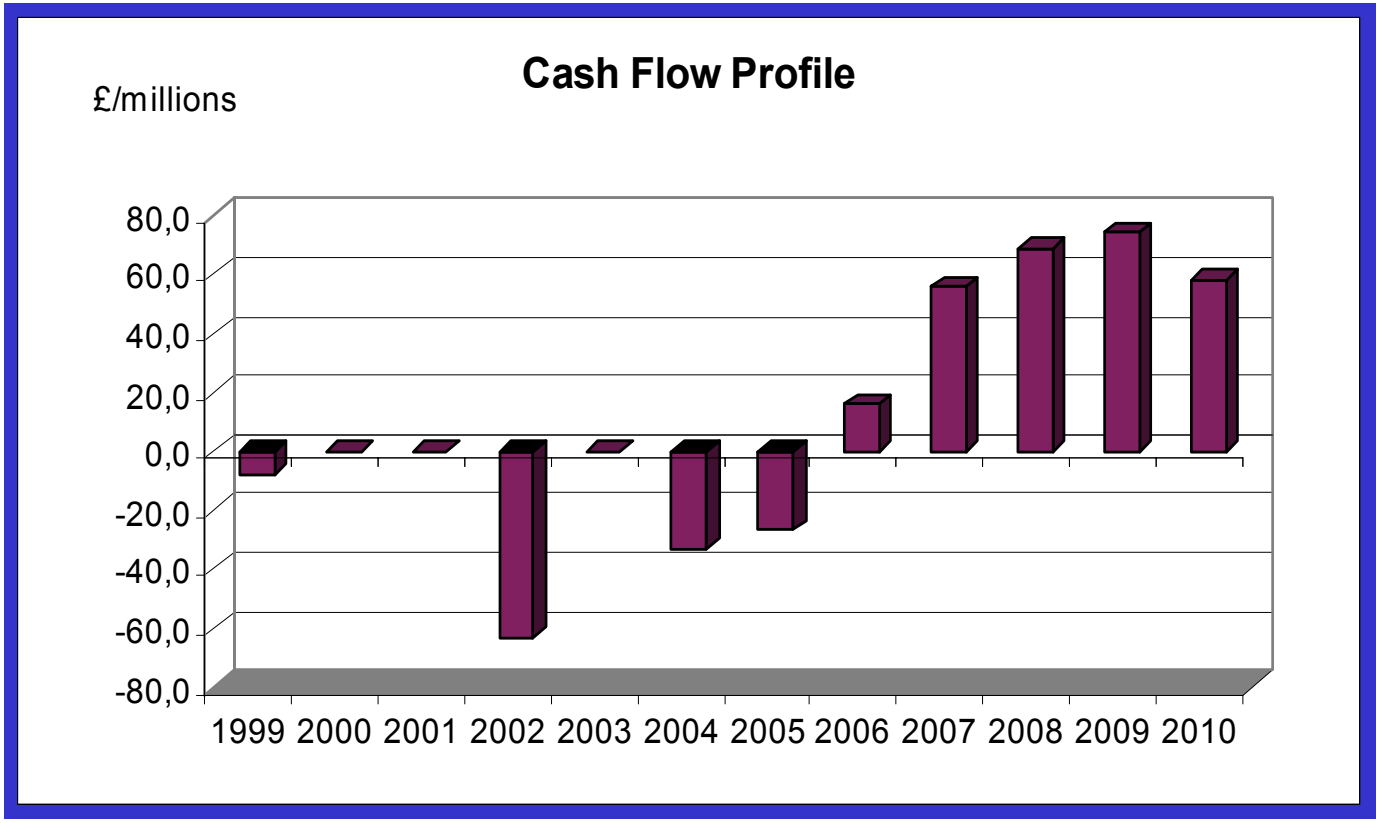
II. Cash Flow Profile (Timeline)



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II. Additional (Option) Input Estimates

- Volatility (std dev) = 35%
- Riskless interest rate = 3%
- Salvage value = £ 5 m

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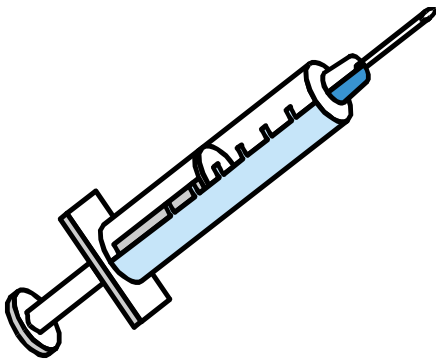
II. Additional (Option) Input Estimates: Option to Expand (Launch Injectable)



- *Expanded project value (with expansion option):* $R = V + \text{Max}(eV - Ie, 0)$

➔ V = underlying project value (oral) following random walk (V_0 = £62.8)

➔ e = 0.6 (60% expansion rate)

[estimated by marketing department]

➔ Ie = £32 m (follow-on cost to add capacity)

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II. Additional (Option) Input Estimates: Option to Abandon During Development

(or Abandon for Salvage/ Sell to Biotech)

- *Project value with abandonment option:* $R' = \text{Max}(R - I_3, S)$

R = value if continue development (including option value to later expand)

I_3 = £63.1 m (3rd stage development costs that can be abandoned)

S = £5 m (resale value guaranteed by a biotech firm interested in acquiring the scientific results)

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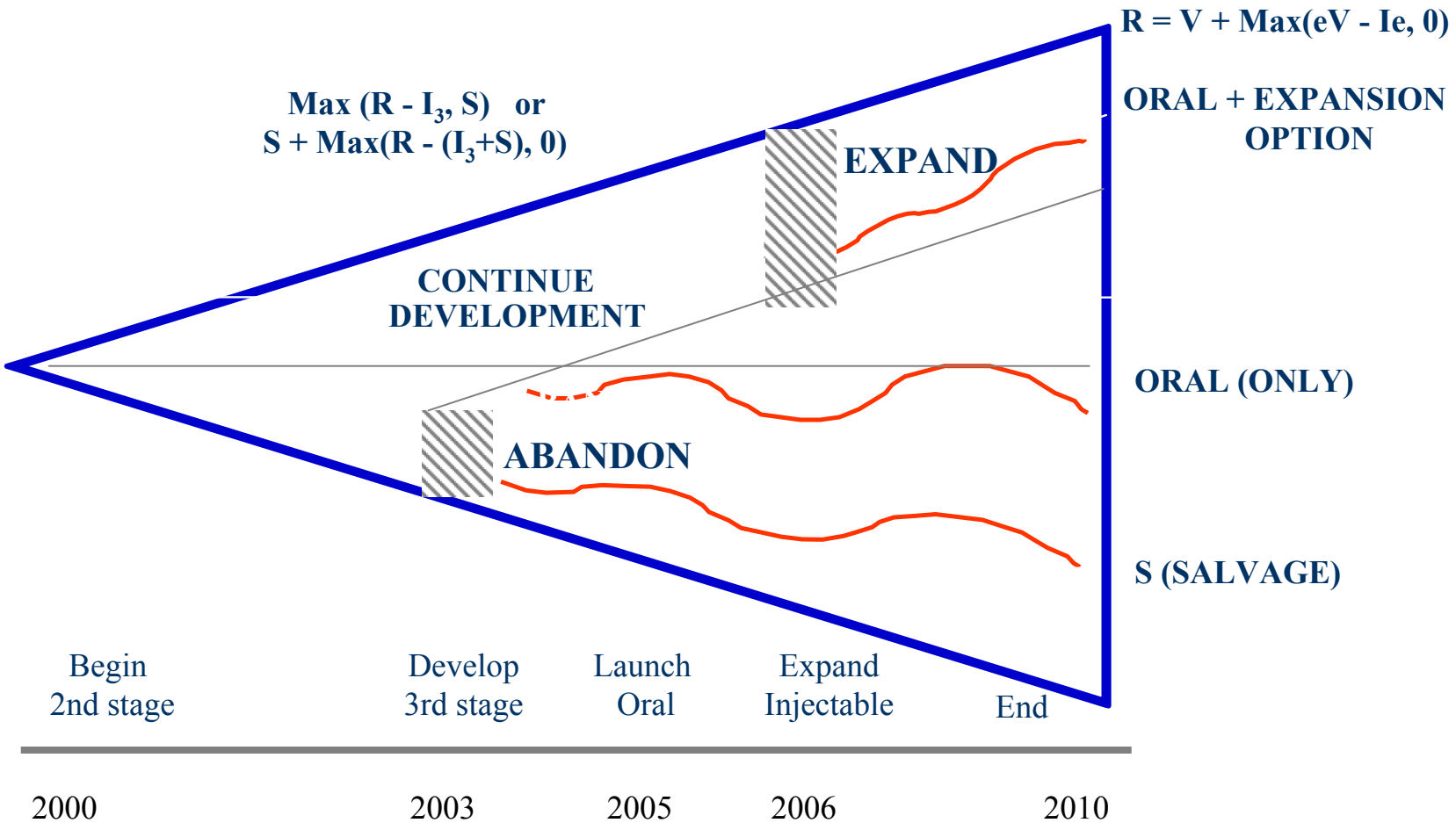
II. Numerical (Binomial) Valuation Model (Accounting for Option Interactions)



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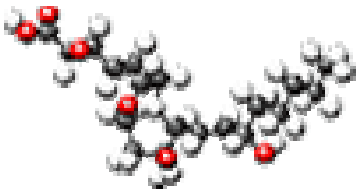
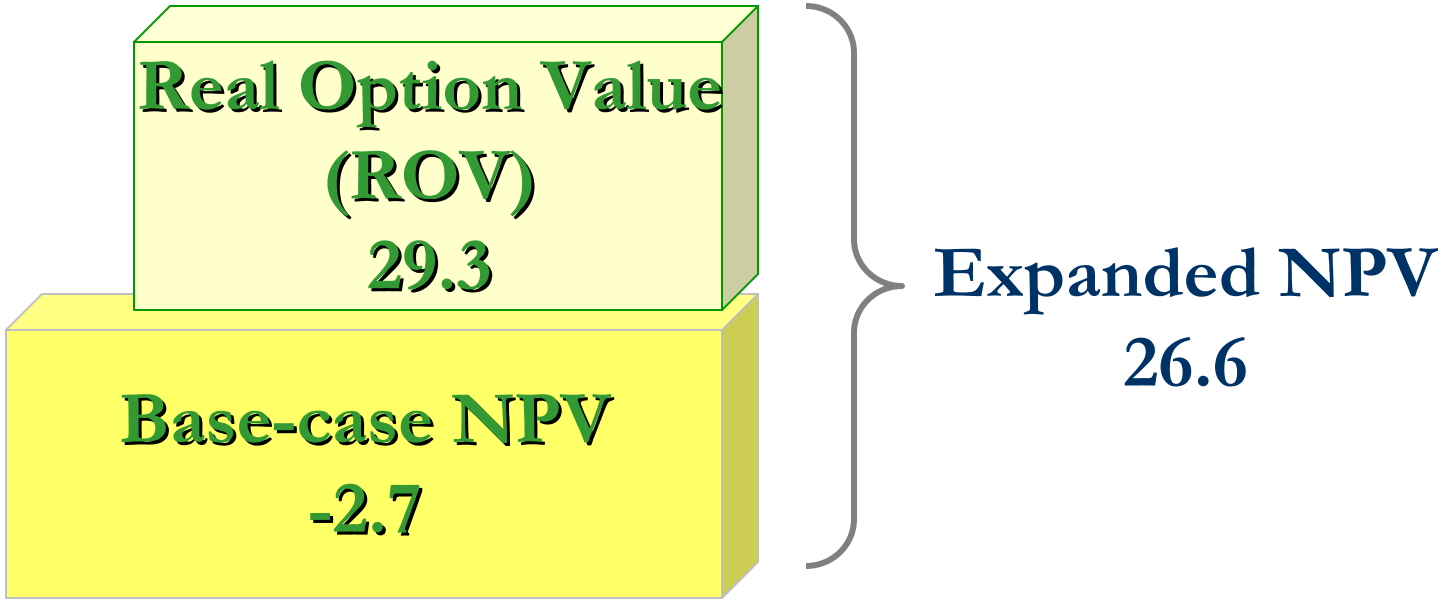
II. Results



Expanded NPV = + 26.6



E-NPV = Base-case NPV + Real Option Value = +26.6

☺ **ROV makes the project worthwhile**

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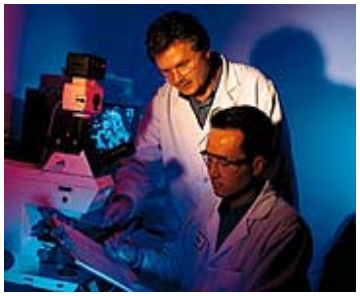
II. Impact Analysis/ Sensitivity to Primary Value Drivers



- Impact Analysis (view Bar Chart)

- Sensitivity of E-NPV to primary value drivers (know what variables to focus on)
  - ➔ Gross project value (driven by demand)
  - ➔ Volatility
  - ➔ Capex (2nd and 3rd stage development costs)
  - ➔ Expansion scale (e)
  - ➔ Salvage value

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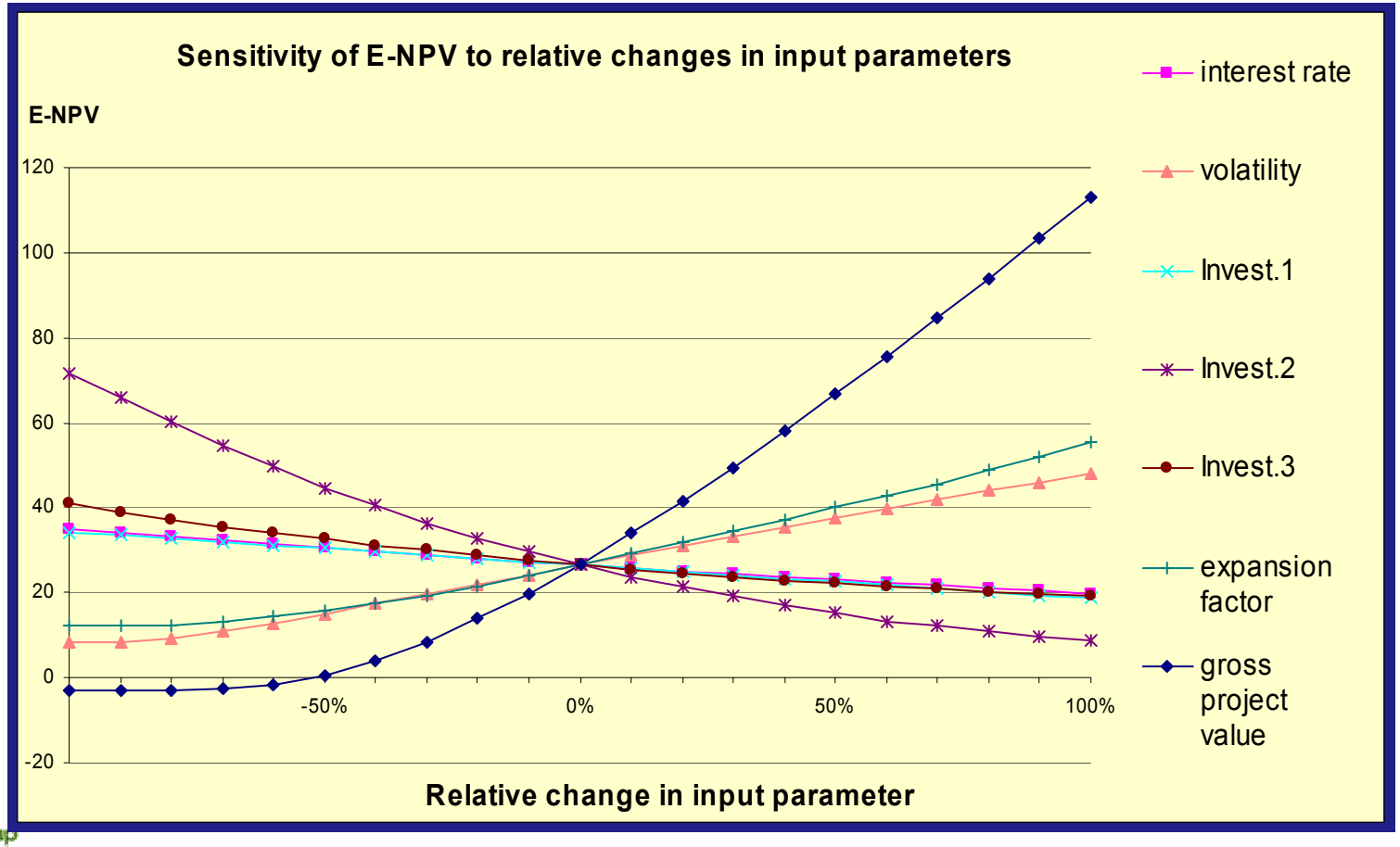
II. Sensitivity of Total Project Value (Expanded-NPV)



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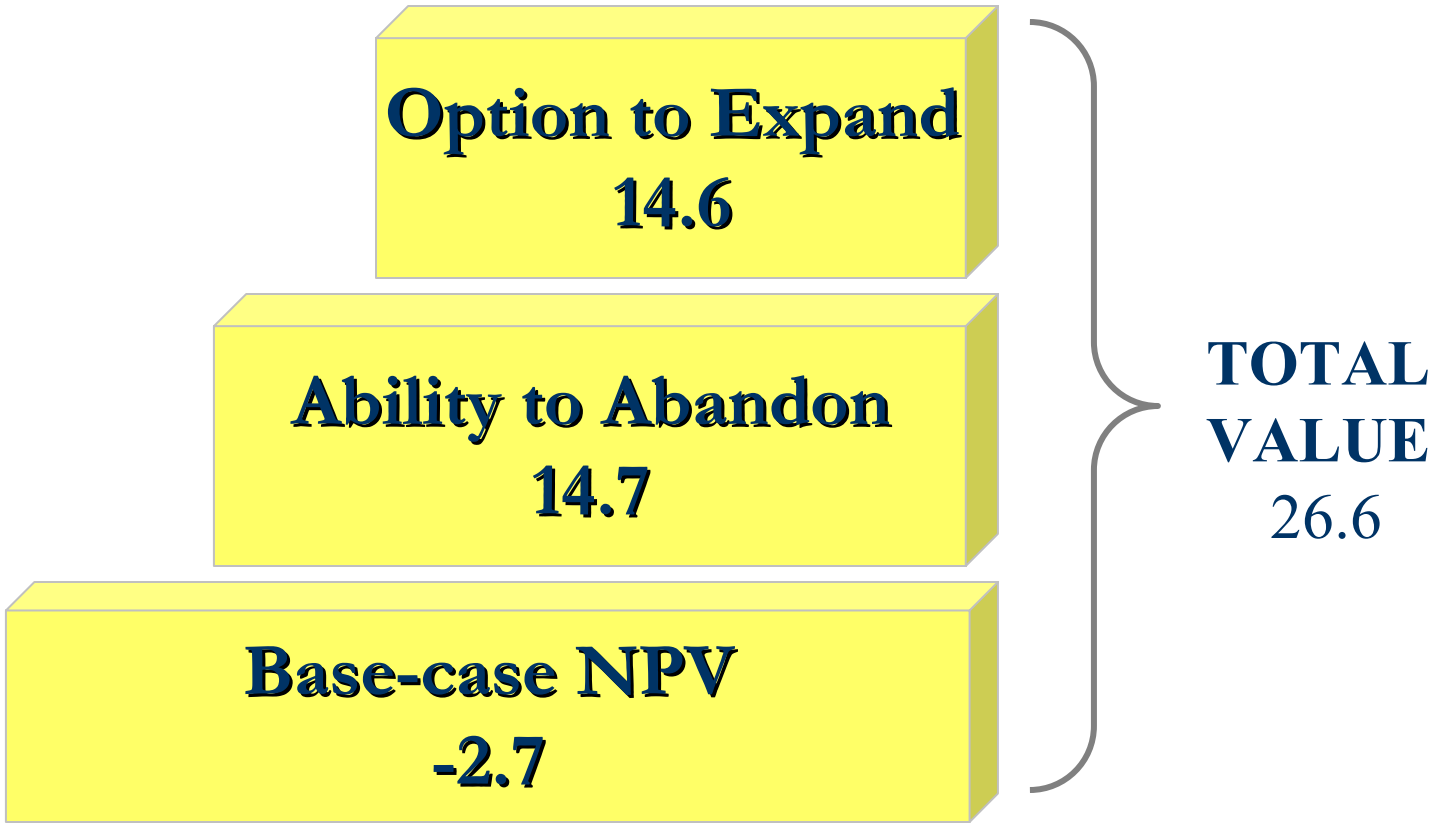
II. Value Contribution/Breakdown (Incremental Value of Each Option/Strategy)



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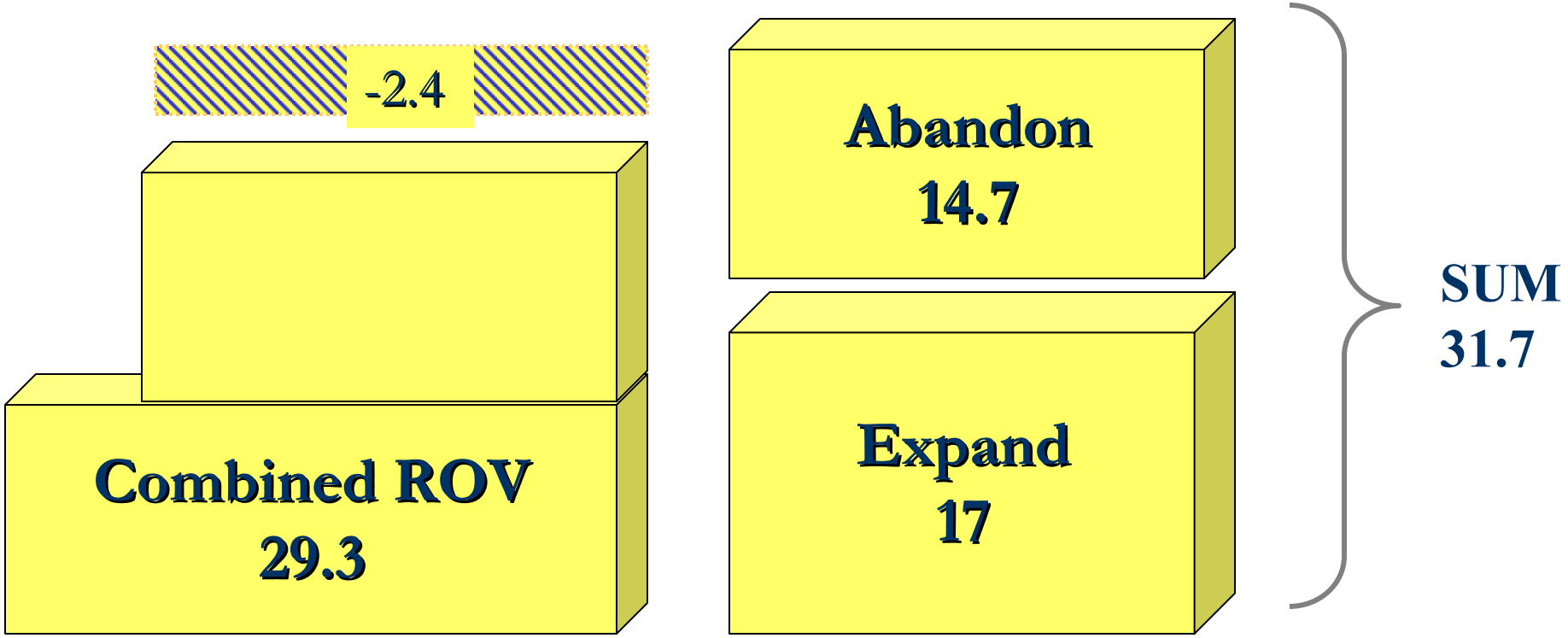
II. Option Interaction (Breakdown)



- Abandonment depends on expansion option
- 😐 Exercising abandonment kills expansion

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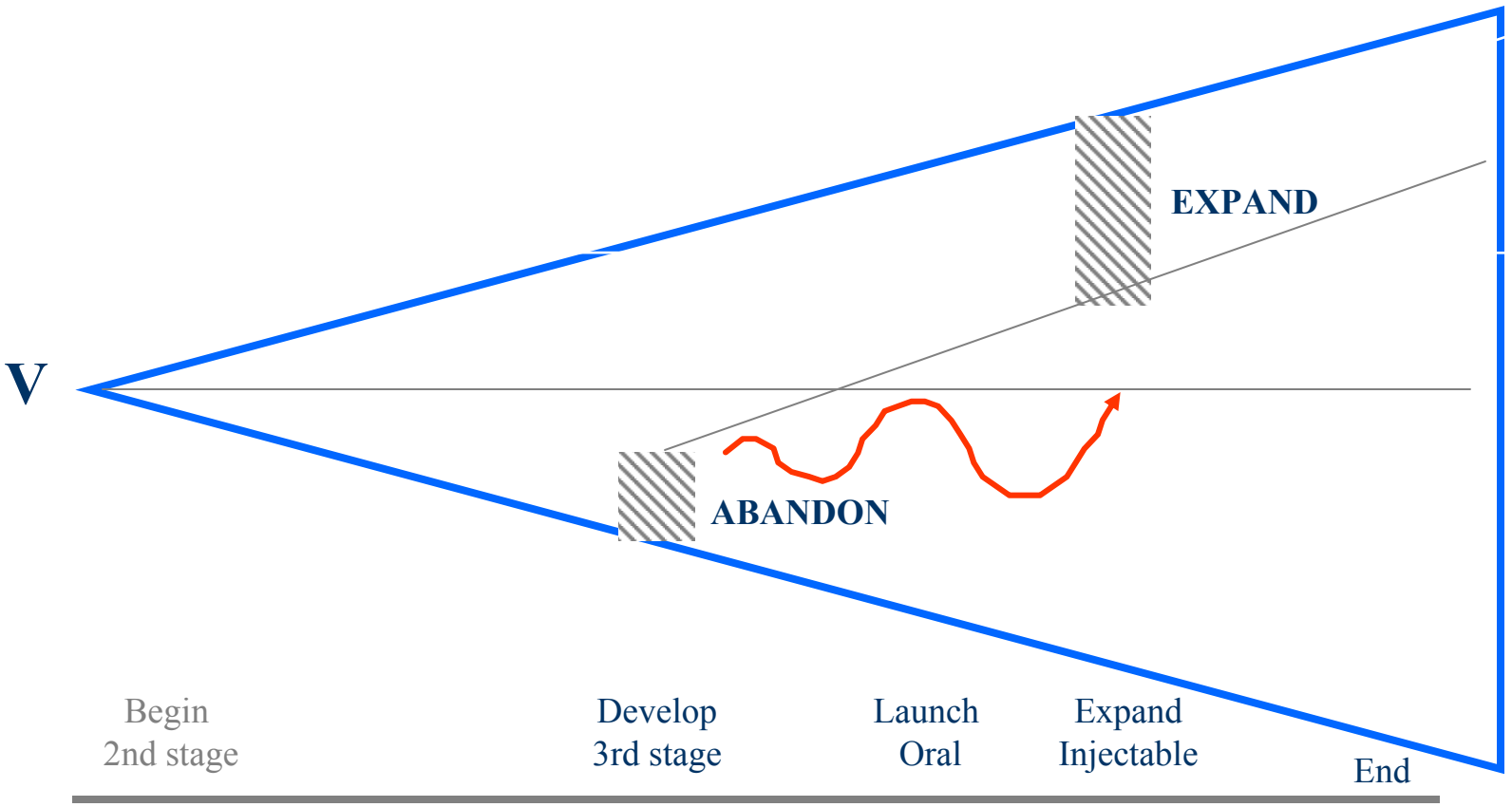
II. Option Interaction



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Phase III. Implementation/Action Plan

- Recommendations
- Contingent Decision Plan
- Operating Policy

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III. Recommendation
(Based on E-NPV, Confidence Profile & Sensitivity Analysis)

- Now (2000) Glaxo should *invest* in the second stage of clinical trials
- In 2003, after technical uncertainty is resolved, Glaxo can decide whether to abandon based on the continuation value, the 3rd stage investment cost estimate, and resale value (to Biotech)
- In 2006, after knowing market demand for the oral (solid) version, Glaxo can decide whether to expand into the hospital market with injectable version

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III. Contingent Decision Plan

DEVELOPMENT PHASE

COMMERCIAL PHASE (Life = 6 years)

BEGIN
2nd STAGE
I_2 = 7.8

Technical uncertainty

Max(R-I_3, S)

DEVELOP
3rd STAGE
I_3 = 63.1

LAUNCH
ORAL

Market demand uncertainty

Max(eV-I_e, 0)

EXPAND
(INJECTABLE)
Ie = 32

e= 0.6

S= 5

ABANDON
(SELL)

0
2000

3
2003

5
2005

6
2006

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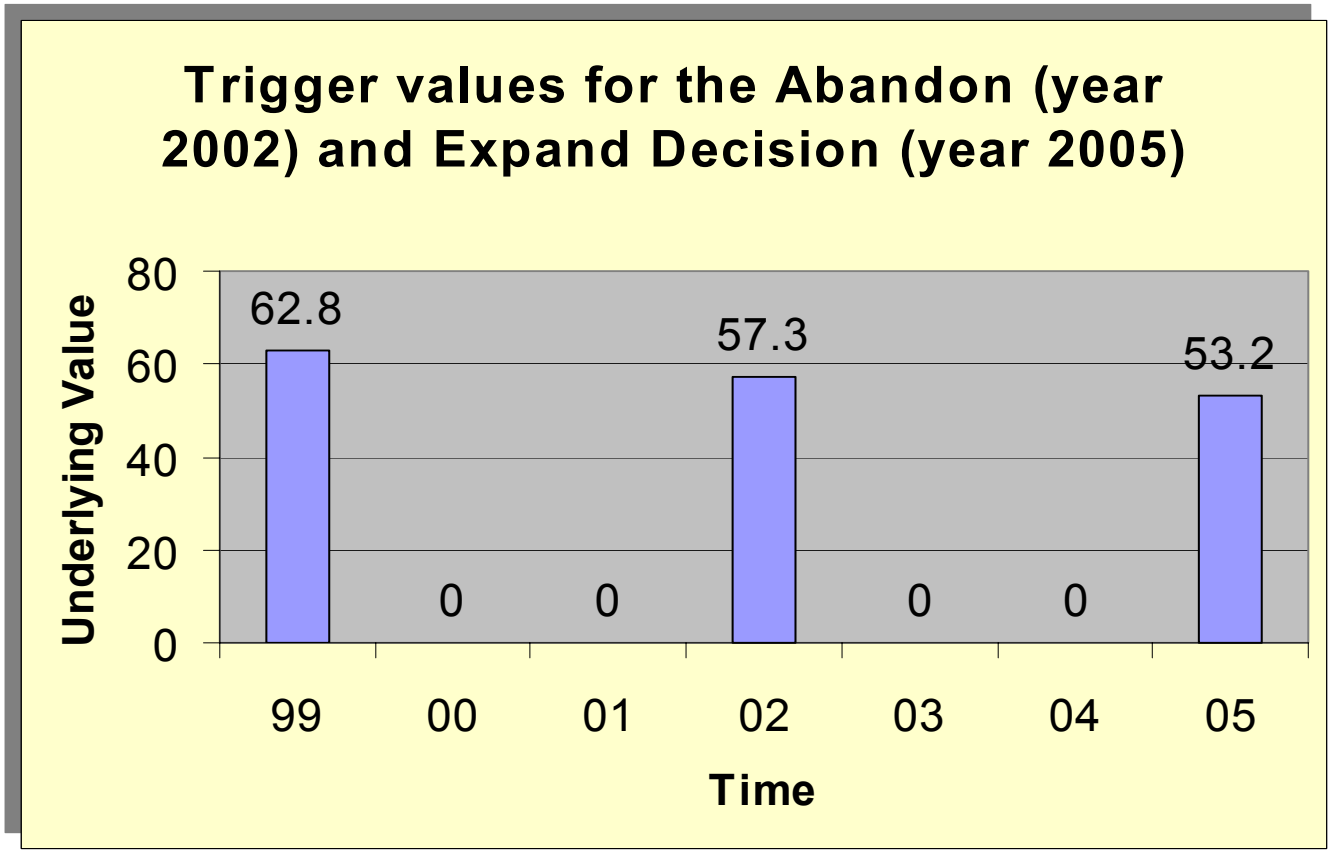
III. Operating Policy and Decision Milestones



III. Musts for Capturing Option Value

- Assign management/team to monitor trigger decisions and exercise options
- Reassess value at future critical milestones
- Align managerial incentives to support/ reward optimal exercise of major real options

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