Advanced Business Development Course

Biotechnology Industry Organization

Valuation and Deal Structuring

Prepared for:

BIO

Advanced Business Development Course

April 2013

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President

DILLONCAPITAL STRATEGIES

Bringing money to medicine©

A Word from the Attorneys

A Word from Grizzled Deal Makers

“The only thing that you can guarantee about any valuation is that it is wrong.”

– Pharma Exec

Valuation and Deal Structuring Program

08:30	**Valuation Concepts and Discounted Cash Flow Models**
09:45	*Break*
10:00	**Valuation Tools and Techniques**
11:00	Case study work
12:30	*Lunch*
13:30	**Forecasting and Market Analysis**
14:30	Case study work (*and break*)
16:00	**Value Sharing and Deal Terms Structuring**
17:00	**Networking Reception**

Before We Get Started

- **Your colleagues here** – Know them & learn from them

You are part of the learning experience here

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- **People's expertise differ** – Be patient and grow

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  - Today
  - Tomorrow
  - Last day

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- **Case study solution** – there is no one correct answer
- **The Ultimate Goal** – Learn, make a deal and have fun.

You are part of the learning experience here

My Background

- **Consulting** – 2003 to 2013. Strategy and Analytics.
- **Small pharma** – 1996 to 2003. Positions of CFO, COO, CEO and Board member.
- **Big Pharma** – 1987 to 1996. Business Development, Evaluation and Analysis, R&D Portfolio Strategy, Long-range Planning, Forecasting and Finance.
- **Education** – Finance degree, MBA and several years teaching at the graduate level. Certified Licensing Professional (CLP).

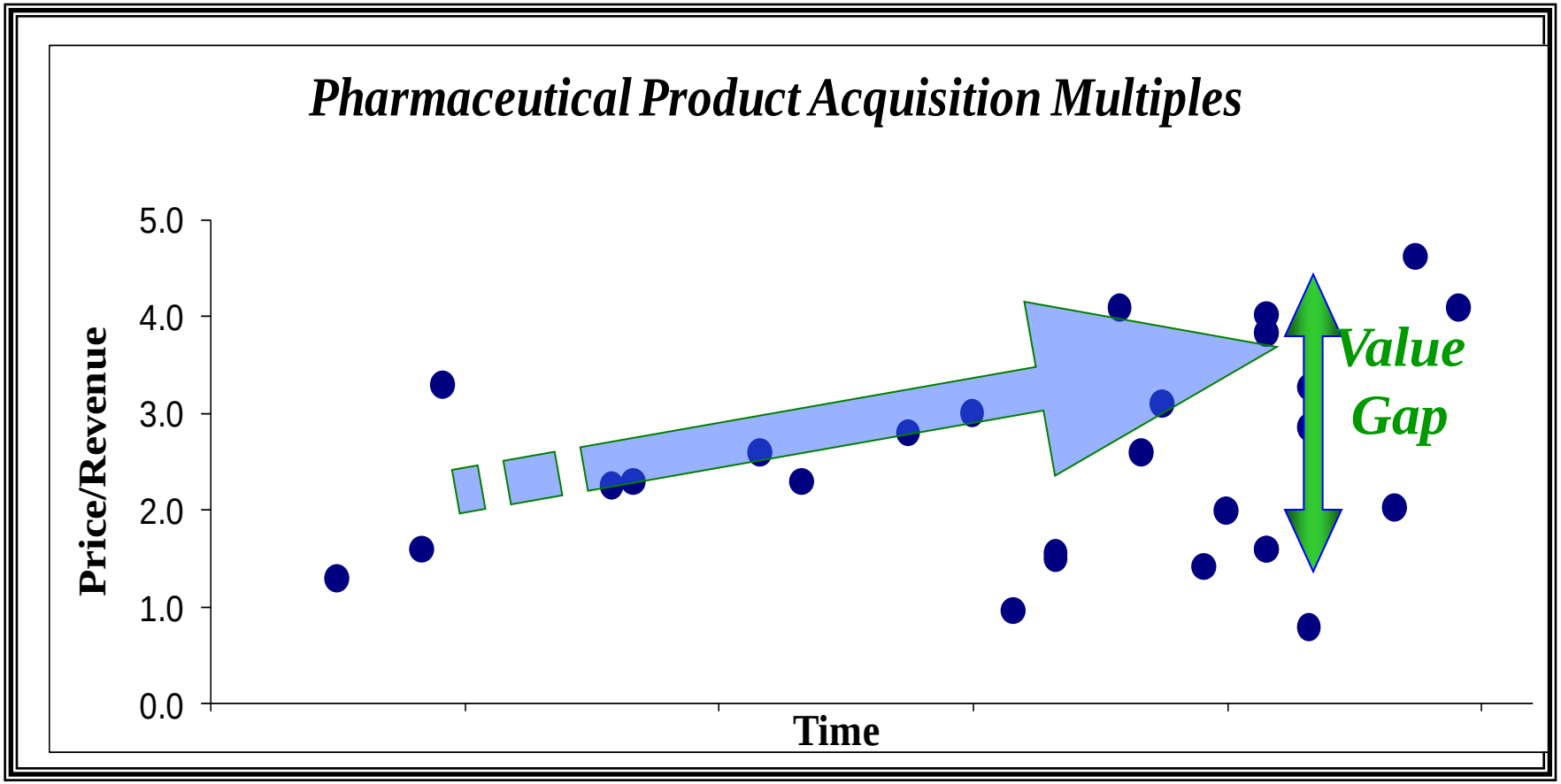
Focus: Partnering/BD, strategic planning, deal strategy, deal structuring, forecasting and valuations

Valuations Challenges

First……

let’s talk a little about deal trends and the reality of value before we worry about the math.

Deal Multiple Trends



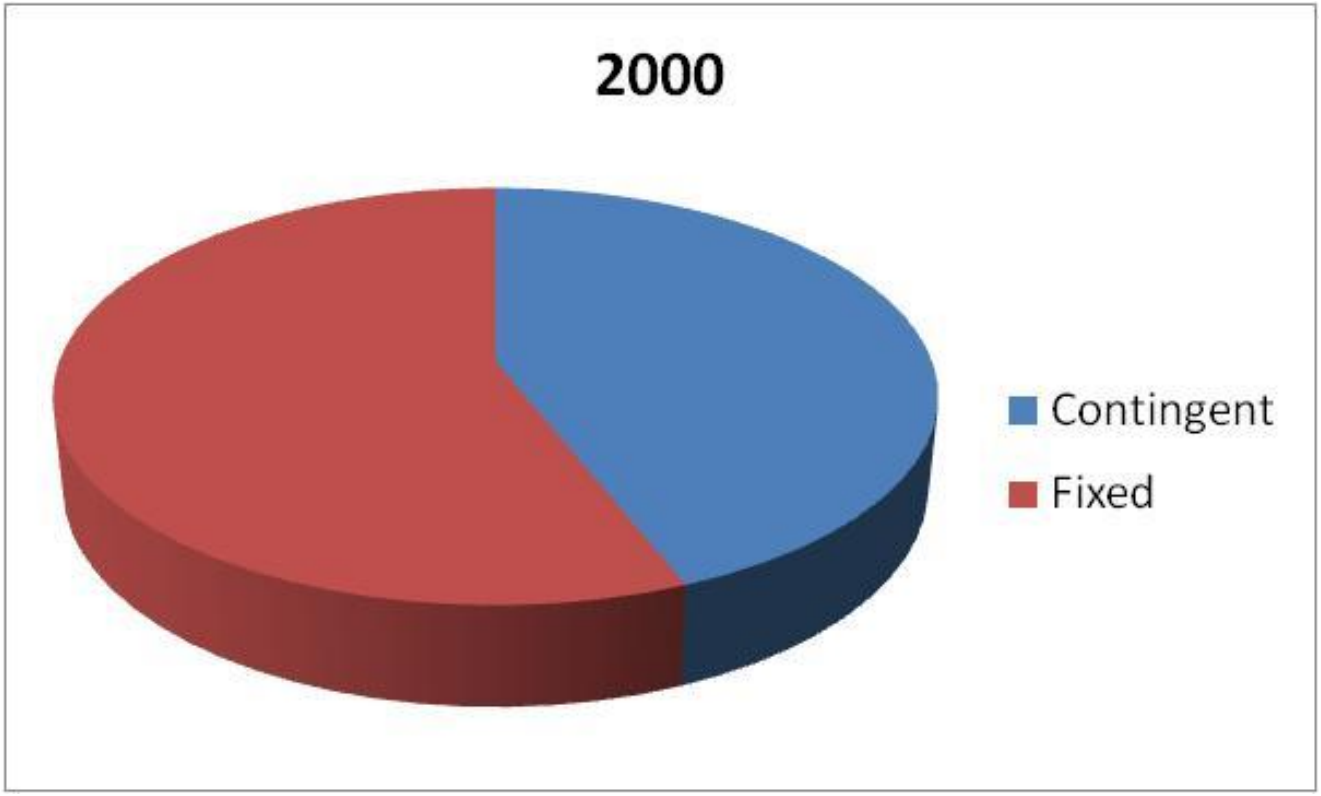
Multiples are a result, not a tool.

Deal Trends

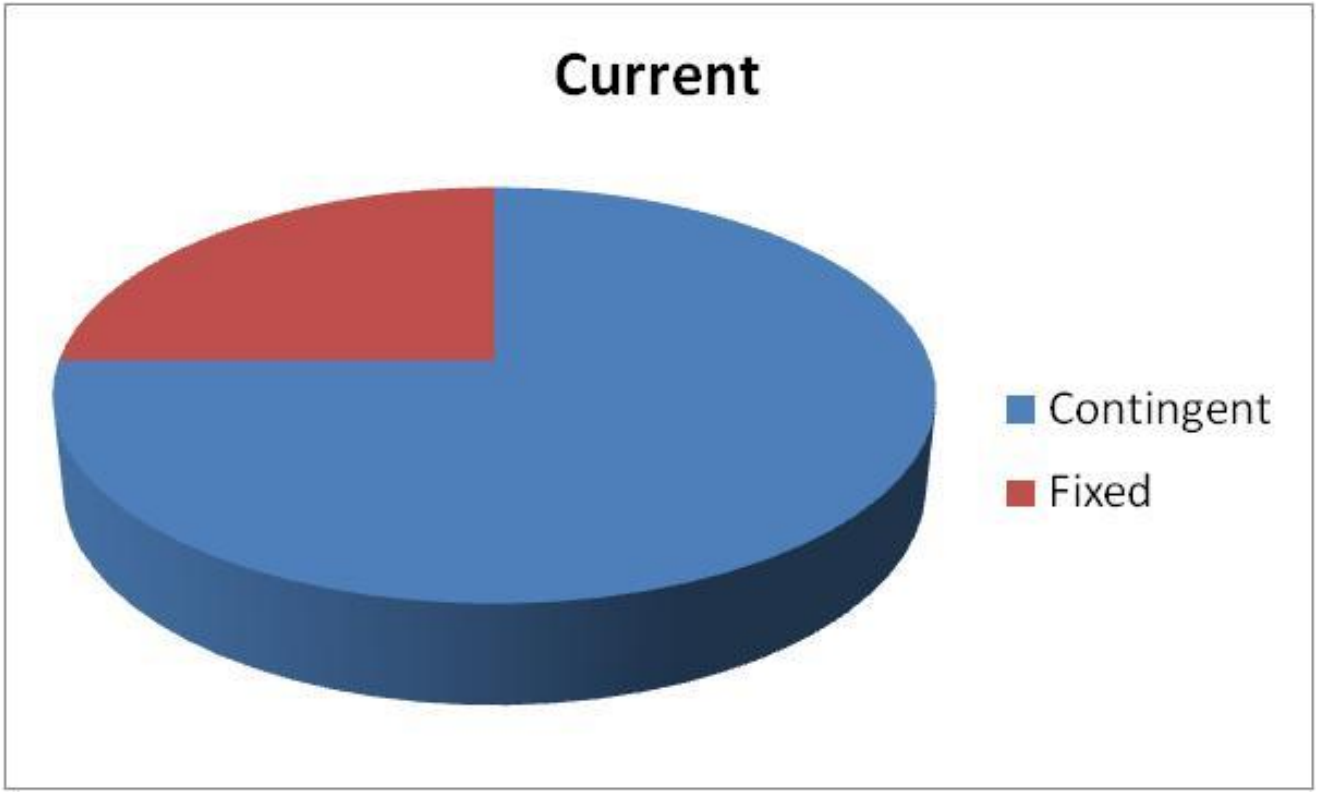
- **Number of Biotech Out-licensing Deals** – Pipeline acquisitions and alliances trending down 50% since 2006.
- **Value of those Deals** – Tripled between 2004 and 2009, down in 2010, but on the rise again 2011 & 2012.
- **Survival of the Bigs** – "Biobuck" acquisitions in vogue. Re-entering early stage market. Partnering with CVC and VCs. Emerging market's higher growth an attractive target. Pricing, access and IP protection increasingly a major valuation factor.
- **Survival of the Smalls** – New technology in high demand, "me-toos" are a tough sell. Option deals and earnouts the new reality. Credit and capital markets expanding.
- **Racing toward the cliff** – Pharma falling off a 2011 – 2014 patent cliff that is erasing $78 billion in revenue on top of the $32 billion it started losing in years just prior to the cliff.

Risk sharing is the structure du jour

Game-changing Deal Structure Trend



Game-changing Deal Structure Trend



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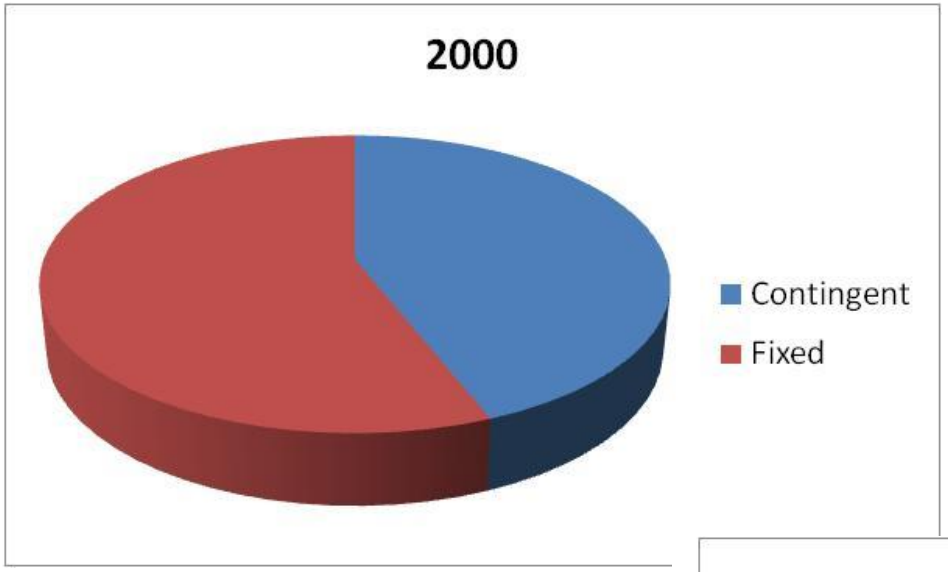
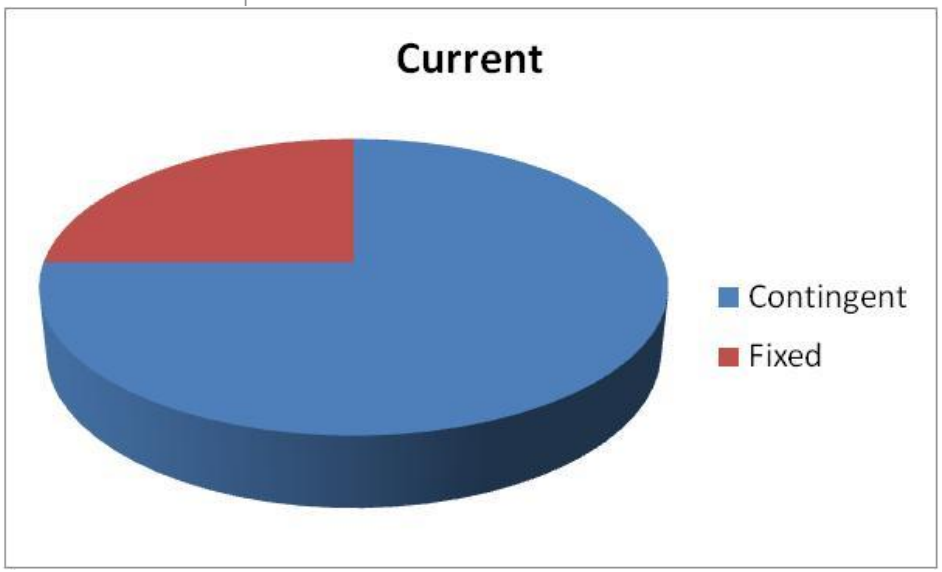




*2006 to 2012 Deal Trends **

2012 Deals Relative to 2006-2012 Averages

- **Preclinical** – Value significantly up at ~$280M, upfronts down at ~10%.
- **Phase I** – Value significantly down at ~$210M, upfronts down at ~10%.
- **Phase II** – Value slightly up at ~$310M, upfronts down at ~15%.
- **Phase III** – Value about average at ~$270M, upfronts down at ~16%.

* Important Note: Published deal values do not include the value of potential royalty steams and other valuable consideration which the parties agreed not to make the monetary value of public.

Reality Set In……

"A lot of people become pessimists from financing optimists."

— CT Jones

What Could Still Cause Increases in Value?

- **Scarcity Value** – Simple supply and demand. More later.
- **Franchise Value** – We are getting better at identifying portfolio synergies, so we are more willing to bid above the stand-alone value of a product, if necessary.
- **Time Value** (of money) – Internal WACC has decreased for many larger companies. Lower discount rates yield higher valuations.

Reality Check: Value = What you can get for it.

Scarcity Value

- **Endangered List**
  - Near-term launch
  - Safe and efficacious (minimal baggage)
  - Peak revenues >$500MM, bonus points if >$1B
  - Manageable development costs and risk
  - Strong IP position and longevity
  - “Specialty” areas with pricing and reimbursement comfort
- **Gaps** - Several Pharmas are forecasting “gaps” that occur simultaneously.
- **Feed the Beast** - Portfolios must “turn” due to aging products and shorter periods of market domination.

Whomever has the gold rules!

Trends in Managing Risk and Sharing Value

- **More Acquisitions, especially "earn-outs"**
- **Still many collaborative deals**
  - A twist on traditional "Option deals"
  - More gambles and rewards being shared
  - Timing and risk assignment increasing in importance
  - Co-marketing/promotion deals far less common
- **More early stage deals**
  - Forecasting can be dicey at best
  - Values are being bid up, but pay-offs are contingent
    - Require more sophisticated valuations and deal structures

Enter the new "norms"

Most Deals Fail

Depending on who you cite the number is 50 – 75%

Curious Fact

Products in an alliance have nearly double the probability of success.

Clue: External diligence > Internal diligence

Valuations Challenges

- Why do different parties usually give the same deal a different valuation?
- How are these values being calculated?
- What assumptions will have to be made?
- What is the best time to do a deal?
- What is the right amount to receive/pay and how can it be structured to reduce my risk?
- How do you strike a balance between what is offered and what works for both parties?

Optimizing Development Product Deal Timing

- Major Quantitative Drivers in Deal Timing
  - Time Value of Money
  - Development Risk
  - Evolving “Proof of Concept”
  - Development Cost Sharing
  - Partner Specific Needs (cash flow, expertise, facilities, etc.)
  - Others as Applicable to the Specific Deal

Optimizing Development Product Deal Timing

- Other Important Factors to Consider
  - A partner may increase probability of development success
  - A partner may have synergistic programs to improve the product or franchise
  - A partner may have ancillary capabilities necessary during the development and pre-commercialization process
  - Relationship may transcend and provide value to other areas of the enterprises

Watch for "hidden" value and "soft" costs

What Drives Value?

- First – What drives value?
  - Meeting an unmet need
  - Discovering a need and satisfying it
  - More effective product (efficacy)
  - Safer or easier to use product
  - Lower costs
  - Risk mitigation
  - IP protection
  - Scarcity, franchise, and time values

Value is in the wallet of the beholder.

Key Variables

- Variables which usually impact value the most:
  - Gross Revenue (price and units)
  - Discount Rate
  - Probability of Technical Success (approval/launch)
  - R&D Cost
  - Rebates, Allowances and Returns (RARs)
  - Sales & Marketing Cost
  - Deal Terms
  - Cost of Goods (increasingly important)

Question Everything!!!

Valuation Methodology

Comparables?

- True comps are rare. Critical info often not made public.

Multiples?

- Variance from average ~2x. Irrelevant unless launched.

Cost Basis?

- Prior R&D spending is not an indicator of future value.

Payback?

- Ignores product lifecycle after payback.

Income (Discounted Cash Flow - NPV)

- Most appropriate for high tech projects
- Risk-adjusting a must for deal structuring
- Used by all In-licensors polled in a large survey

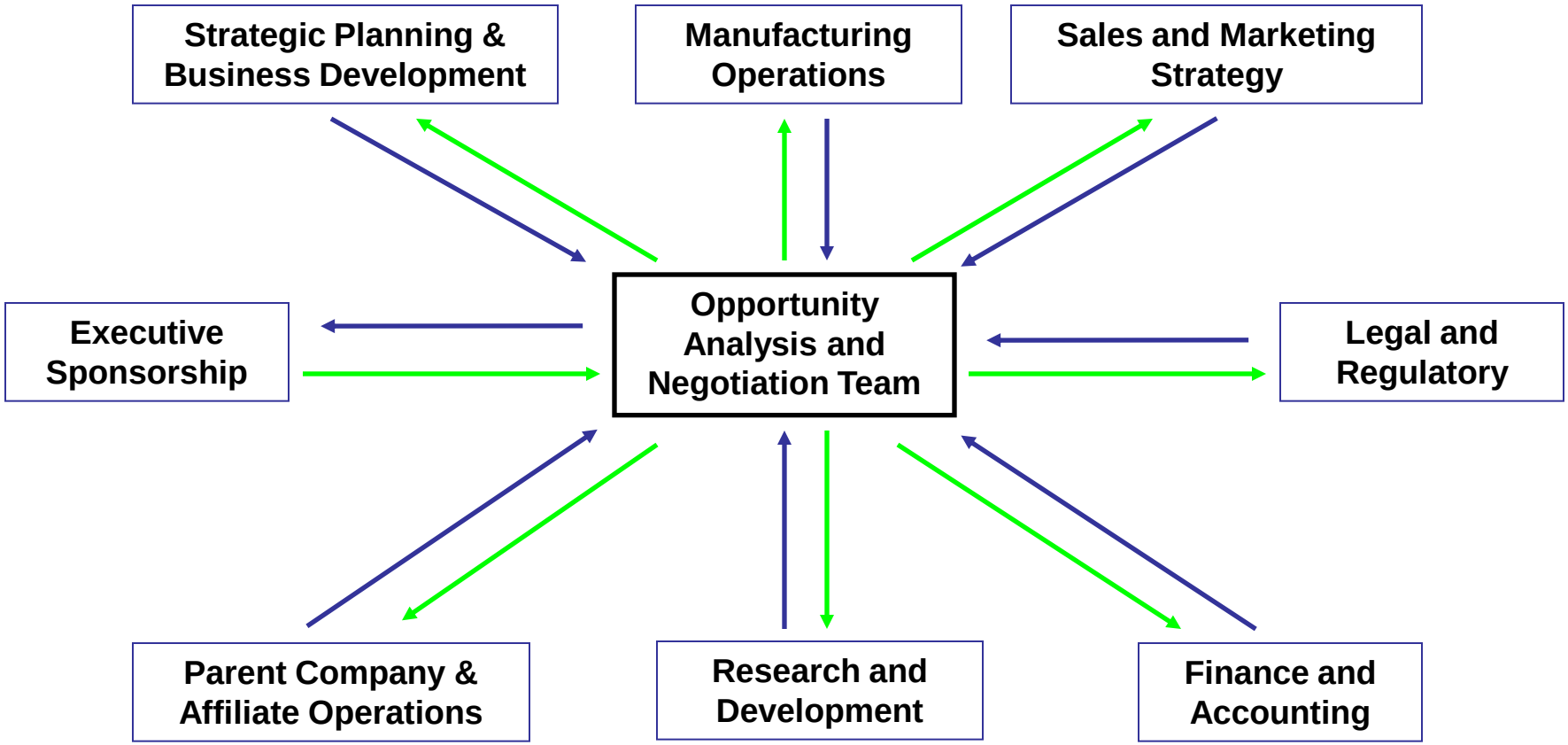
Focus on Risk and Return ("Cash is King")

Why Do Analysis and Valuations?

- Provides defendable claim of value (98% of "buy-side says they use rNPV on all PC and later deals)
- Solid basis for negotiations
- Real-time deal terms strategy simulation
- Basis for comparison to other opportunities
- Support go / no-go decisions
- Develop operating plans / budgets
- Flush-out issues and "surprises"
- NPV can easily be back-calculated to get IRR

The "devil" really is in the details.

Deal Team Concept



Revenue

- Build-up from detail
  - Patient-based
  - Dosing frequency / units / pricing strategy
  - Life cycle (patents, equivalents, population)

  - ---- more later

This is usually the dominating value driver

Costs and Expenses

- Usually requires multiple scenarios for early stage technology
- R&D, launch, sales & marketing, G&A, *etc*.
- Estimate scale-up capital costs
- Variable and new fixed costs
- Working capital burden
- Marginal tax impact (non-cash deductions)
- Include deal costs (fees, amortization, *etc*.)

Think incrementally

Discount Rates

- Components of the discount rate
  - Inflation (when using nominal or current dollars)
  - Real risk-free rate (T-bill premium, same maturity)
  - Company's incremental cost of capital (risk premiums)
- Considerations
  - Use probability of success for project risk
  - Use care when mixing real and nominal figures
  - Rates differ widely by company
    - Possible higher values with established deal partners

Repeat – Leave project risk out of it!

Discount Rates (continued)

- Which rate to use?
  - Weighted average cost of capital (WACC) for the firms involved
  - Average or typical WACC for firms in the industry
  - Hurdle rate or IRR expected by top management
  - Project-specific discount rates
  - Appropriate use of real vs. nominal discount rates

Discount Rates (continued)

Cost of Equity Capital

E = I + (M - I) + S + IP =

Return for a specific Investment	E		
Risk-free rate	I	3.32%	10 year Treasury
Return for the equity market as a whole	M	10.72%	
Market risk premium	(M - I)	7.40%	
Small company/Liquidity premium	S	0.00%	
Industry Premium	IP	4.00%	
Total Cost of Equity Capital		14.72%	
Rounded Cost of Equity Capital		14.7%	

Weighted Average Cost of Capital (WACC)

(IRR Debt * (1-Tax Rate) * Debt:Capital Ratio) + IRR Equity * Equity:Capital Ratio

IRR Debt	7.90%	Baa bond yield
Average Tax Rate	38.00%	
Average Debt:Capital Ratio	4.00%	
WACC (Discount Rate)	14.33%	
Rounded Discount Rate	14.3%	
Marginal Tax Rate	34%	

Risk Assessment

- Probabilities of Success Categories
  - Development (will the science work?)
  - Regulatory (will it be approved for marketing?)
  - Commercial (will the market be as we expected?)
- Considerations
  - Qualitative and quantitative rating system
  - Specific to the project being considered
  - Consider the resources and capabilities available
  - Break down by phase or decision points

Risk changes over time

Timing Matters

Period:	1	2	3	4	5
Discount rate:	***15%***				
Payments:	10	10	10	10	10
Discount Factor	1.00	0.87	0.76	0.66	0.57
NPV of each Payment	10.00	8.70	7.56	6.58	5.72
NPV of Payment Stream	***38.55***				

Period:	1	2	3	4	5
Payments:	0	2	3	15	30
Discount Factor	1.00	0.87	0.76	0.66	0.57
NPV of each Payment	0.00	1.74	2.27	9.86	17.15
NPV of Payment Stream	***31.02***				

Period:	1	2	3	4	5
Payments:	0	0	0	0	50
Discount Factor	1.00	0.87	0.76	0.66	0.57
NPV of each Payment	0.00	0.00	0.00	0.00	28.59
NPV of Payment Stream	***28.59***				

Discount Rate Matters

Period:	0	1	2	3	4
Discount rate:	***5%***				
Payments:	10	10	10	10	10
Discount Factor	1.00	0.95	0.91	0.86	0.82
NPV of each Payment	10.00	9.52	9.07	8.64	8.23
NPV of Payment Stream	***45.46***				

Discount rate:	***25%***				
Payments:	10	10	10	10	10
Discount Factor	1.00	0.80	0.64	0.51	0.41
NPV of each Payment	10.00	8.00	6.40	5.12	4.10
NPV of Payment Stream	***33.62***				

Discount rate:	***50%***				
Payments:	10	10	10	10	10
Discount Factor	1.00	0.67	0.44	0.30	0.20
NPV of each Payment	10.00	6.67	4.44	2.96	1.98
NPV of Payment Stream	***26.05***				

War-gaming Tools

Seat of the pants……

Sopwith Camel

War-gaming Weapons

……..or “heads up display”

F-14 Tomcat

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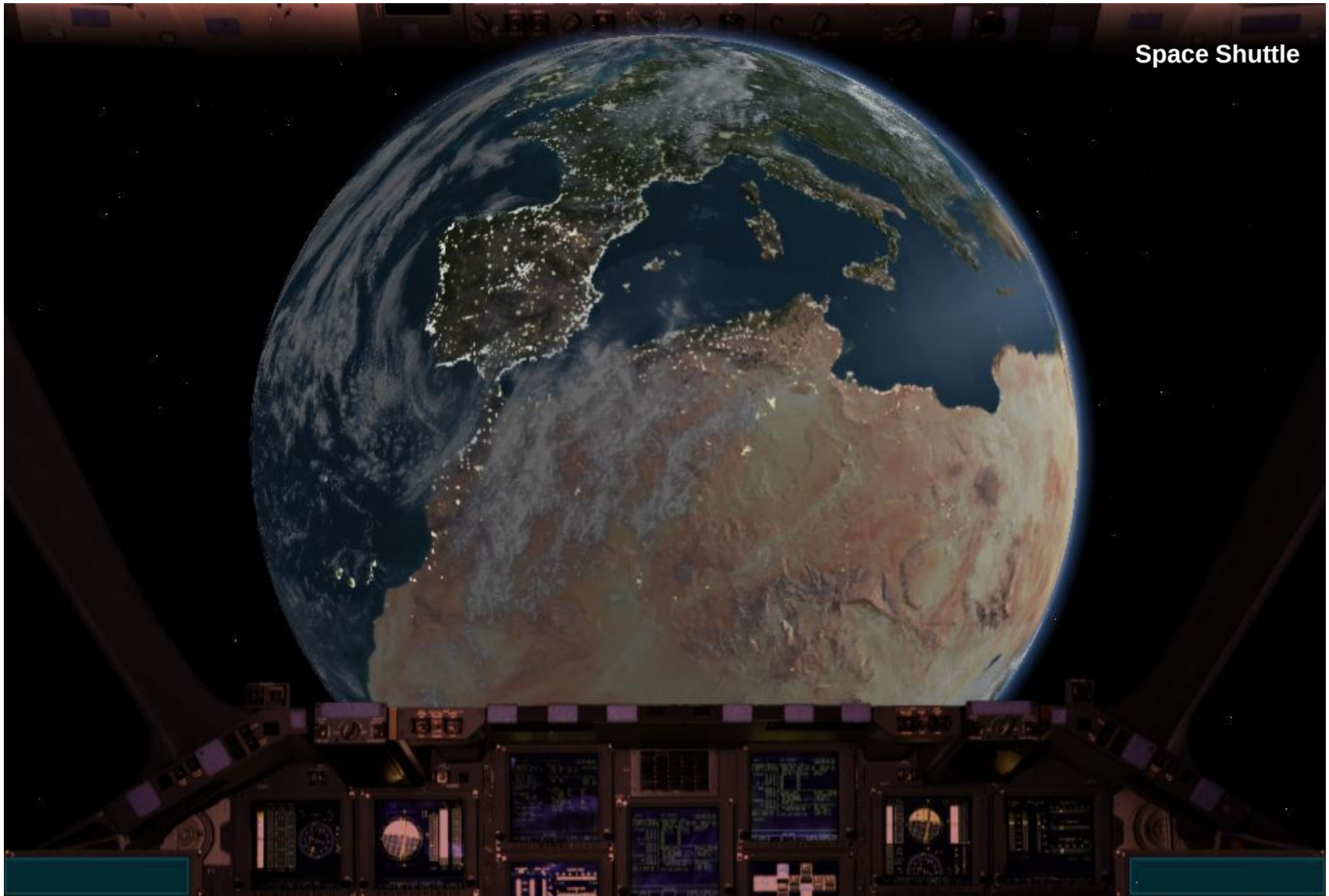
War-gaming Weapons

……..or world domination



Step into the Cockpit

DCS Opportunity Valuation and Gaming Model

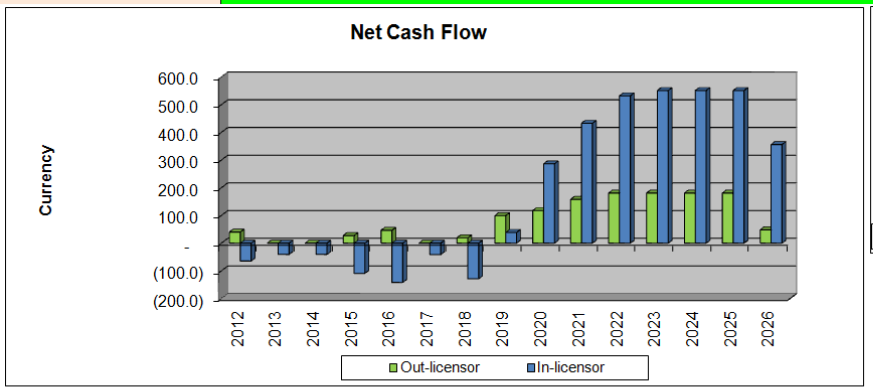
Sheet: Cockpit
Product: Product X
In-Licensor: Pharma
Out-Licensor: Biotech
License Expiration: 04-Feb-13

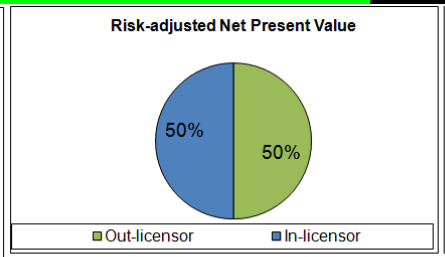
237 days remaining on license period.

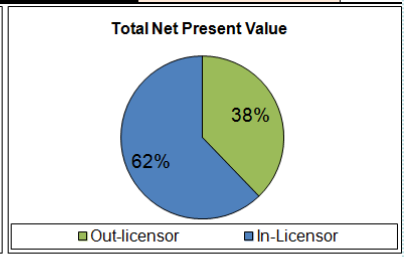
		Total Product Value		Value to Out-licensor		Value to In-licensor	
First Year of Cash Flow	2012	Value Components	Consolidated	Value Components	Consolidated	Value Components	Consolidated
Real Discount Rate	8.74%						
Nominal Discount Rate	12.00%						
Inflation Factor	1.03						
Marginal Tax Rate	32.0%	NPV without Terminal Value	1,478.4	NPV without Terminal Value	587.4	NPV without Terminal Value	891.0
Working Capital as % Revenue	10.0%	NPV of Terminal Value	139.0	NPV of Terminal Value	23.9	NPV of Terminal Value	115.1
Terminal Value Growth Rate	-33.0%						
Scenario Multiples		Terminal Value as % Total NPV	8.6%	Terminal Value as % Total NPV	3.9%	Terminal Value as % Total NPV	11.4%
Sales	1.0						
Cost of Goods Sold	1.0	**Total NPV**	**1,617.4**	**Total NPV**	**611.3**	**Total NPV**	**1,006.1**
Sales & Marketing	1.0						
Research & Development	1.0	Probability-Weighted NPV	291.2	Probability-Weighted NPV	145.7	Probability-Weighted NPV	145.6
Other Operating Expenses	1.0			NPV as % of Total NPV	37.8%	NPV as % of Total NPV	62.2%
Name of 4th Territory	ROW			NPV as % of Prob-Weighted NPV	50.0%	NPV as % of Prob-Weighted NPV	50.0%
Figures in:	Euros (millions)						

Royalty Structure					
Territory	Tier 1 Royalty	Tier 2 Royalty Threshold	Tier 2 Royalty Rate	Tier 3 Royalty Threshold	Tier 3 Royalty Rate
United States	12.0%	200	17.0%	400	20.0%
Europe	12.0%	200	17.0%	400	20.0%
Japan	12.0%	200	17.0%	400	20.0%
ROW	12.0%	200	17.0%	400	20.0%

Calculated Royalty Rate	
Territory	2012
United States	12.0%
Europe	12.0%
Japan	12.0%
ROW	12.0%







NOTES: Excel pie charts display negative values as positive slices So, if Total NPV is negative for either partner, the pie chart will display misleading share slices. The Terminal Value amount does not display as a bar in the Net Cash Flow graph because it is not an actual cash flow, however it is added to the total product valuation.

BREAK!

(return at 10:00am)

Model Orientation

We'll spend a few minutes here to walk through the case study valuation model.

Today's Program

08:30	**Valuation Concepts and Discounted Cash Flow Models**
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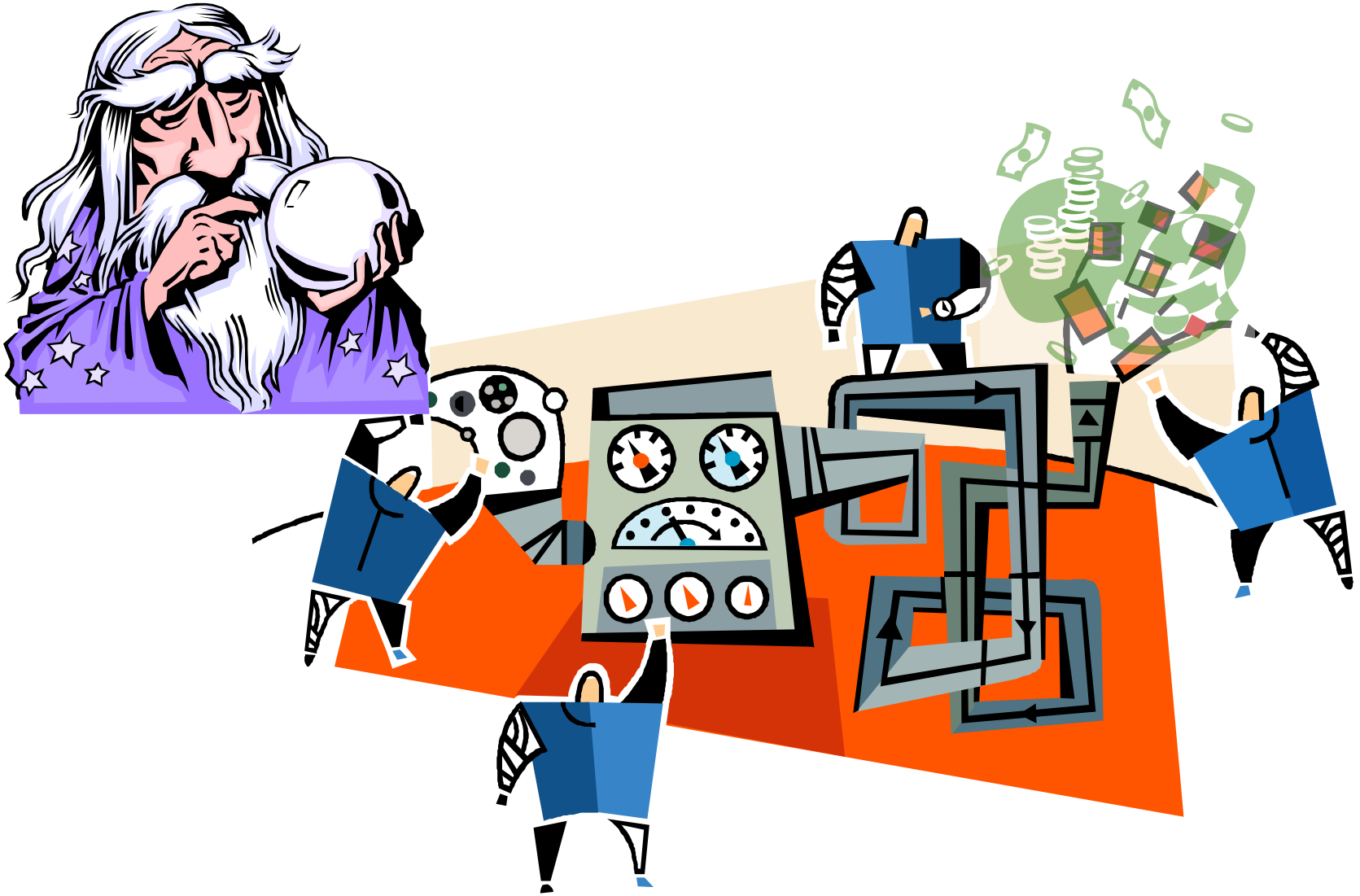
17:00	**Close**

Sell-side Forecasting Process



Valuation Tools

- Commonly used
  - Net present value, NPV
  - Probability-adjusted (rNPV) or expected NPV (eNPV)
  - Decision tree analysis (DTA), quasi option analysis
  - Internal rate of return, IRR

- Less frequently used (and frequently misused)
  - Payback period (in conjunction with other methods)
  - Real Options, using option valuation formulas
  - Monte Carlo Simulation (covered after lunch)

Nearly all "buy-siders" use NPV and rNPV

Net Present Value (NPV)

Definition

Present value of a project's cash flows – including the invested capital (project cost) discounted at the firm's cost of capital

Equation

$$NPV = CF_0 + CF_1/(1+WACC)^1 + CF_2/(1+WACC)^2 + \ldots CF_n/(1+WACC)^n$$

Example

Project A costs $20 M upfront, and CF are projected to be $10 M, $8 M, $6 M, and $2 M in years 1-4 respectively; the firm's cost of capital is 10%

$$\text{So, } NPV = -20 + 10/(1.1) + 8/(1.1)^2 + 6/(1.1)^3 + 2/(1.1)^4 = \$1.576\ M$$

Decision Rule

If NPV is positive, consider doing the project; the more positive, the better.

NPV Pros and Cons

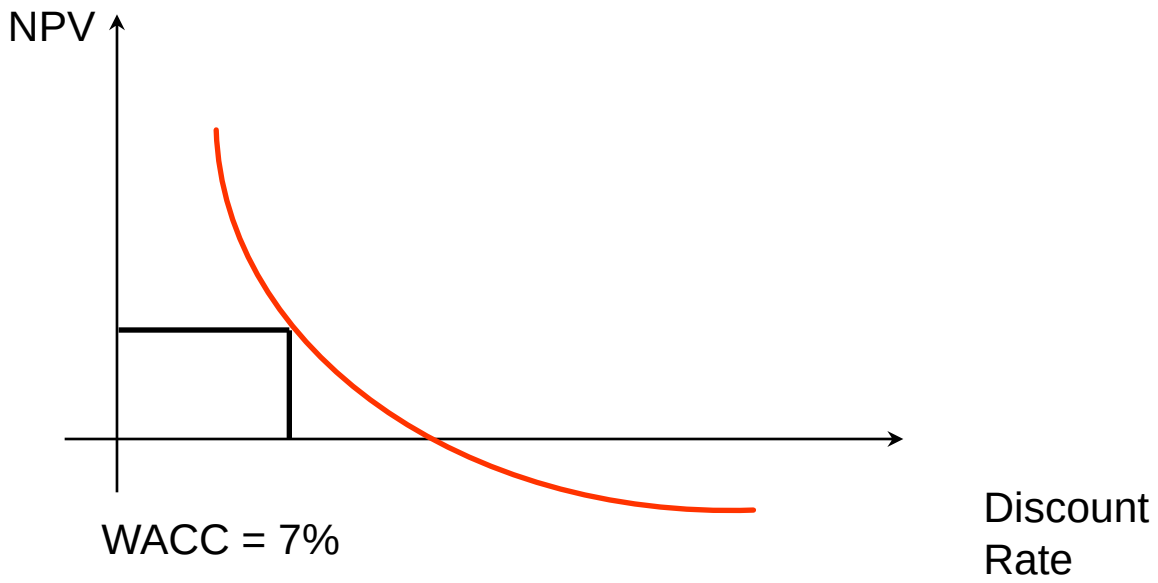
Pros

- Assumes that the reinvestment rate of the cash flows is the cost of capital which is conceptually correct
- If mutually exclusive projects are being considered and the NPV and IRR give different ranking results, the NPV method is considered by financial experts to be superior, since it maximizes shareholders' wealth

Cons

- Does not explicitly consider size of the return in relation to the amount invested
- Highly sensitive to WACC, and this can be difficult to calculate accurately; also WACC changes over time
- IRR is preferred to NPV by many corporate executives

NPV vs. Discount Rate



Feasibility: Project must have NPV>0

Internal Rate of Return (IRR): Discount rate at which NPV=0

Risk-adjusted Net Present Value (rNPV)

Definition

- Same as NPV, except that future cash flows are probability-adjusted prior to discounting them at WACC

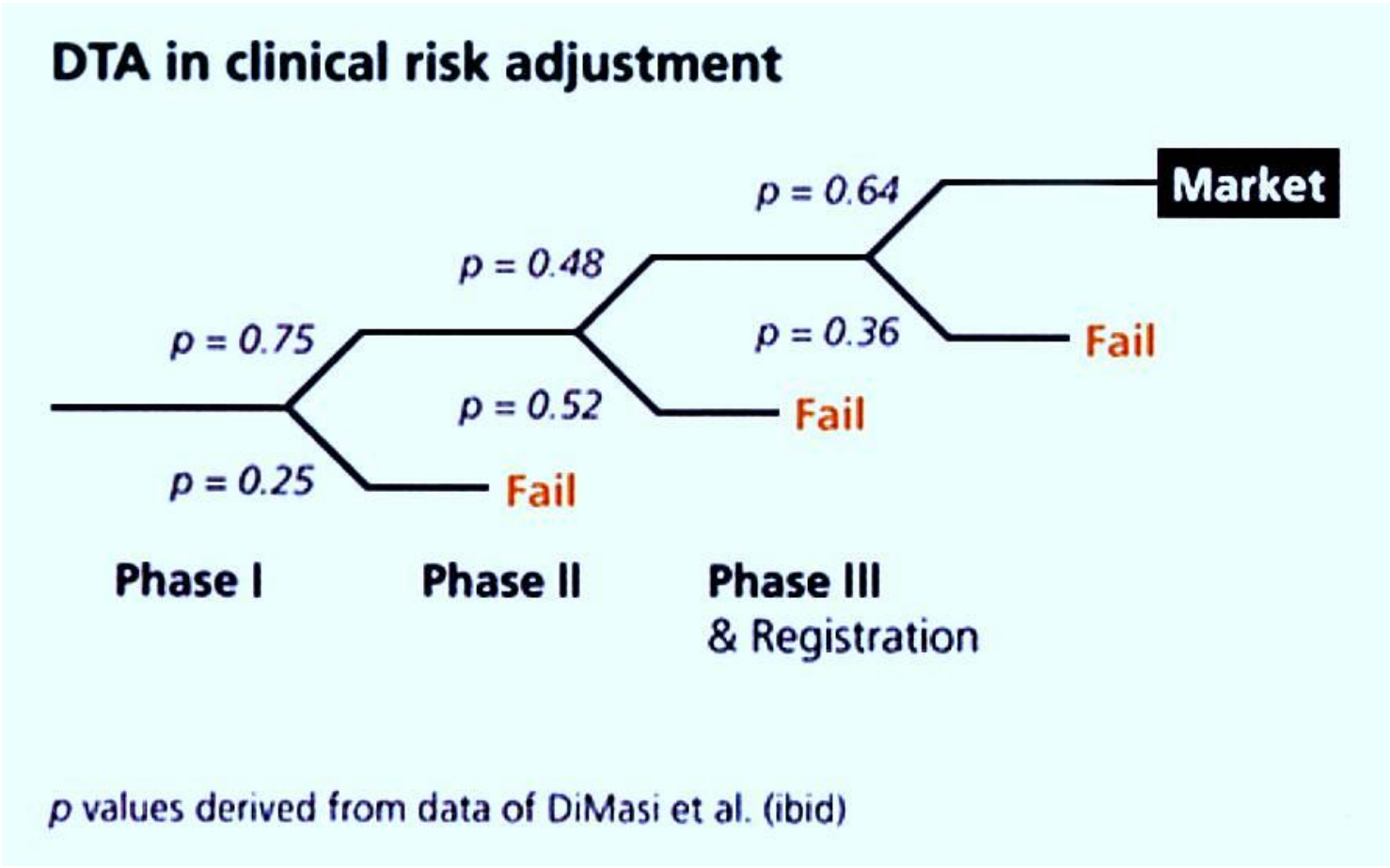
Pros

- For projects with significant uncertainties in CFs, such as drugs in various stages of development, results are more accurate than NPV
- Is a kind of decision tree model that reflects managers' ability to stop the project in case of technological failure

Cons

- Same as NPV, except that future cash flows are probability-adjusted prior to discounting them at WACC
- Not as widely used and understood as NPV

Decision Tree Analysis



Decision Tree Pros and Cons

Pros

- Forces a process to consider all possible outcomes
- Is a fairly simple and familiar technique to many people

Cons

- Real life choices not always clear cut.
- Models can become cumbersome and trees “bushy”
- Arguably better for project management or simple option selection than for valuations

Internal Rate of Return

Definition

The overall rate of return on a project, determined by solving for the rate of return for which the NPV of a project is zero

Equation

$$NPV = 0 = CF_0 + CF_1/(1+IRR)^1 + CF_2/(1+IRR)^2 + \ldots CF_n/(1+IRR)^n$$

Example

Project A costs $20 M upfront, and CF are projected to be $10 M, $8 M, $6 M, and $2 M in years 1-4 respectively

$$\text{So, if } NPV = 0 = -20 + 10/(1+IRR) + 8/(1+IRR)^2 + 6/(1+IRR)^3 + 2/(1+IRR)^4, \text{ then } IRR = 14.5\%$$

Decision Rule

If IRR > WACC, consider accepting the project; note that WACC may be adjusted up or down to compensate for risk. The higher the IRR, the better

IRR Pros and Cons

Pros

- Measures profitability as a percentage, showing the return on each dollar invested
- Tells you how much the project return could fall (in percentage terms) before the firm's capital is at risk
- IRR is preferred to NPV by many corporate executives

Cons

- Assumes that the reinvestment rate of the cash flows is the IRR; this can be less realistic than using WACC as the reinvestment rate
- If mutually exclusive projects are being considered and the NPV and IRR give different ranking results, the NPV method is considered by financial experts to be superior, because it measures incremental stakeholder wealth once the minimum IRR hurdle is cleared

Payback Period

Definition

The number of years required to recover the costs of the investment

Equation

Payback period = yrs before full recovery + unrecovered cost at start of last yr / CF during the last yr

Example

Year	0	1	2	3	4
Cash flow, CF	-20	10	8	6	2
Cumulative CF	-20	-10	-2	4	6

Payback period = 2 + 2/6 = 2.33 years

Decision Rule

If payback period < benchmark payback period, consider accepting the project; the shorter the payback period, the better.

Payback Period Pros and Cons

Pros

- Is a good measure of project liquidity and riskiness: the shorter the payback, the greater the liquidity; also, distant cash flows are riskier than near cash flows

Cons

- Ignores the time value of money
- Ignores cash flows beyond the payback period

Real Options

Definition

The right, but not the obligation, to undertake or abandon a future project as a result of incurring the cost of a current one

Equation

Black-Scholes equation (to be discussed further)

Example

Company is building a pilot plant

Cost of plant buys "right" to expand

Anticipates expanding capacity in 3 years

Anticipates entering new markets

Decision rule: If NPV of pilot project + call option value of expansion project > 0, undertake project.

Real Options Pros and Cons

Pros

- When applied properly, can capture value of having choices later as a result of making certain decision(s) today
- Uses a well-established pricing model (Black-Scholes equation) by analogy to financial options

Cons

- Difficult to “map” real option variables onto financial option variables
- Difficult to estimate variability accurately, leading to wide variation in real option pricing
- Not routinely used outside of academic / financial expert circles

Variables for Option Pricing

S = Stock Price (Present value of assets)

K = Strike Price (Expenditure to acquire assets)

t = Time to expiration at T (Time decision may be deferred)

r = Risk-free rate (Time value of money)

σ^2= Variance on return of underlying (Riskiness of project assets)

Black-Scholes Equation

$$c(S,t) = SN(d_1) - Ke^{-r(T-t)}N(d_2)$$

X

$$d_1 = \frac{\ln(S/K) - (r + {}_{2}\sigma^{2})(T-t)}{X \quad \sigma\sqrt{T-t}}$$

$$d_2 = d_1 - \sigma\sqrt{T-t}$$

$N(.)$

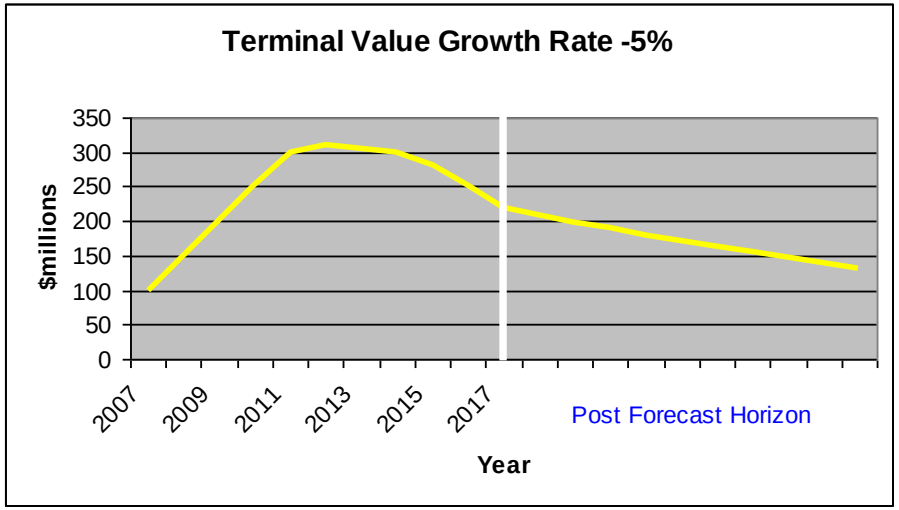
- Used thousands of time daily on options exchanges
- Based on stochastic differential equations
- Widely available as calculator feature or add-in

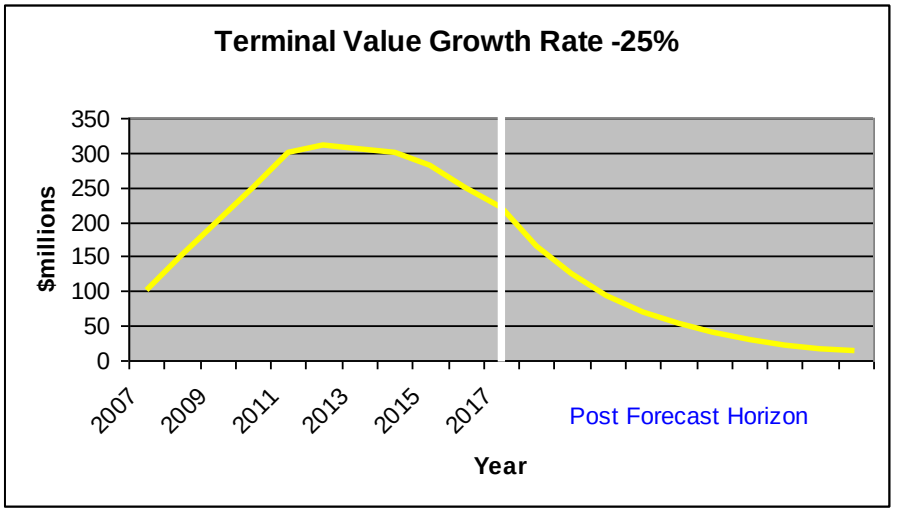
Other Important Valuation Considerations

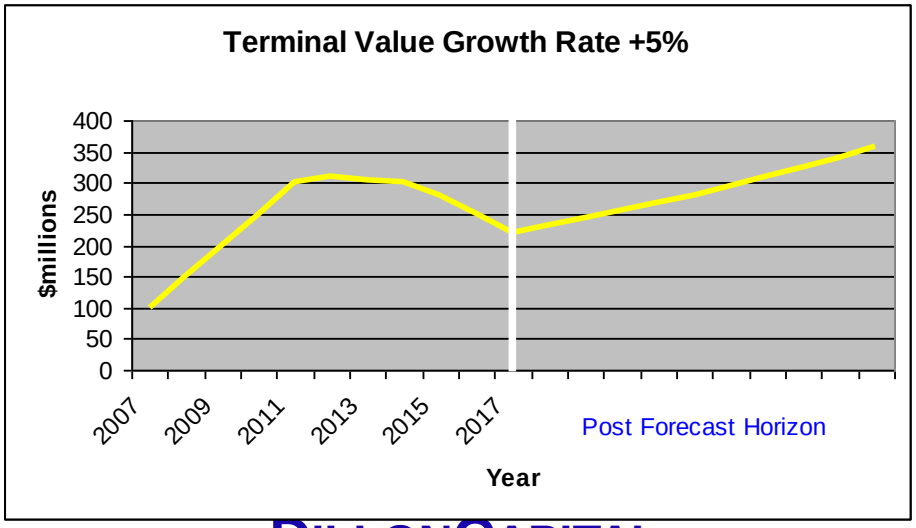
- Terminal Value
  - Estimates the total value of the program for the years after the last year of the cash flow forecast.
  - Our model uses a perpetuity calculation (preferred method).
  - The model input is expressed as a percentage growth (i.e. 5% indicates 5% cash flow growth forever, -5% indicates 5% decline annually until zero is theoretically reached)
  - Terminal value can be a substantial value component, so be careful using and interpreting it.

Other Important Valuation Considerations

Terminal Value Examples







Other Important Valuation Considerations

- Working Capital
  - Working capital is (current assets – current liabilities).
  - It's considered an "investment" to support daily operations.
  - As operations grow, more working capital investment is required.
  - A typical pharma company adds working capital at a rate or 10% - 15% of incremental revenue.
  - Our model accepts inputs expressed as a percentage and adds it as a separate line after tax.

Other Important Valuation Considerations

- Inflation Factor
  - For purposes of our model, we use this to calculate the proper discount rate to use.
  - Remember, the nominal rate includes inflation and the real rate does not.
  - If our forecast has inflation incorporated in it, then we should use the nominal rate. If the forecast does not have inflation in it, then we should use the real rate.
  - The model defaults to the nominal rate unless we enter an "inflation factor" to calculate the real rate.
  - IRR is usually expressed as a rate including inflation (nominal).
  - If you want to achieve the IRR, but have a forecast without inflation, input the inflation factor and the real rate will be calculated.
  - To input 3% inflation, type the factor "1.03" in the field provided.
  - I'll describe this more during the case study…….

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

— Warren Buffet

CASE STUDY – until 12:30

LUNCH – 12:30 – 13:30

Today's Program

08:30	**Valuation Concepts and Discounted Cash Flow Models**
09:45	*Break*
10:00	**Valuation Tools and Techniques**
11:00	Case study work
12:30	*Lunch*
13:30	**Forecasting and Market Analysis**
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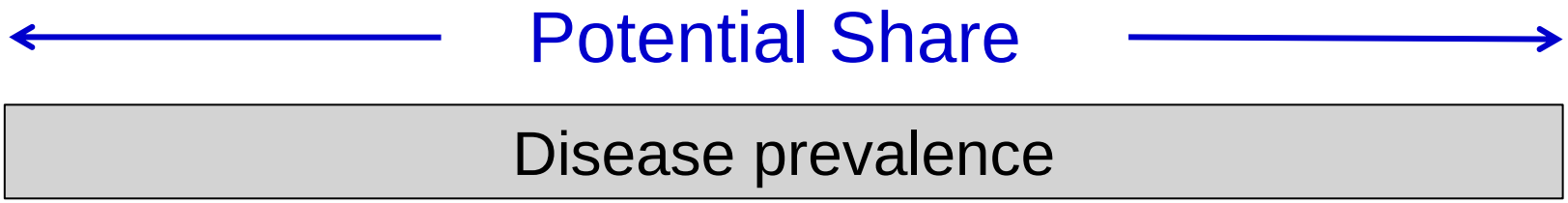
16:00	**Value Sharing and Deal Terms Structuring**
17:00	**Close**

Major Revenue Forecasting Considerations

- Epidemiology (patient basis)
  - Prevalence, incidence and patient flow
- Treatment protocol
  - Doctor's preference and managed care requirements
- Dosing regimen
- Compliance and persistence
- Competitive set (market basis)
  - Marketed and in-development
  - Historical and forecast usage
- Pricing and reimbursement
- Market lifecycle
  - Line extensions and generic entry

Watch for trends

Share of Market Potential



100%

0%

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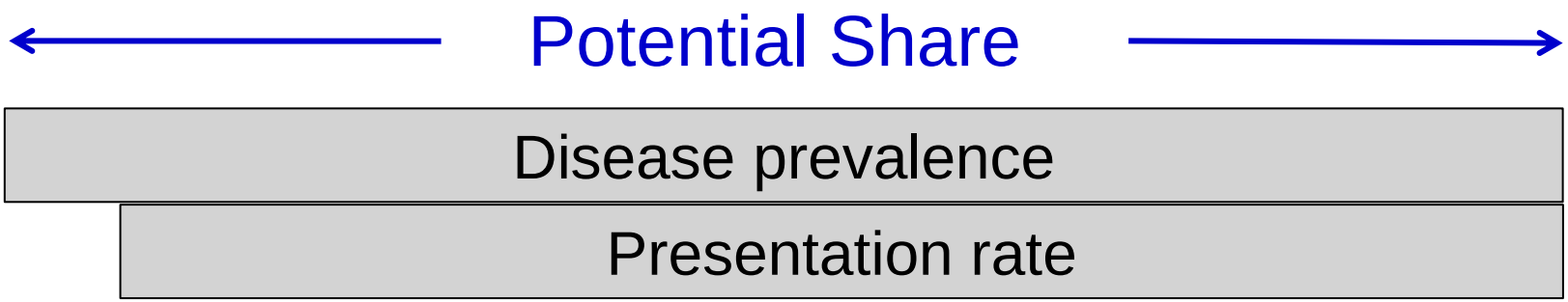
Share of Market Potential



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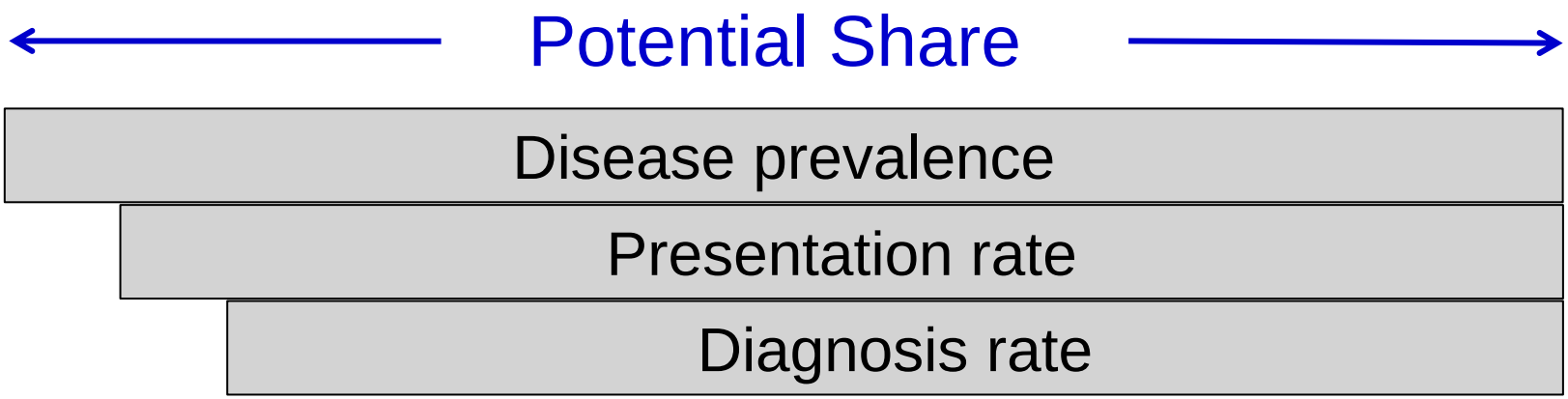
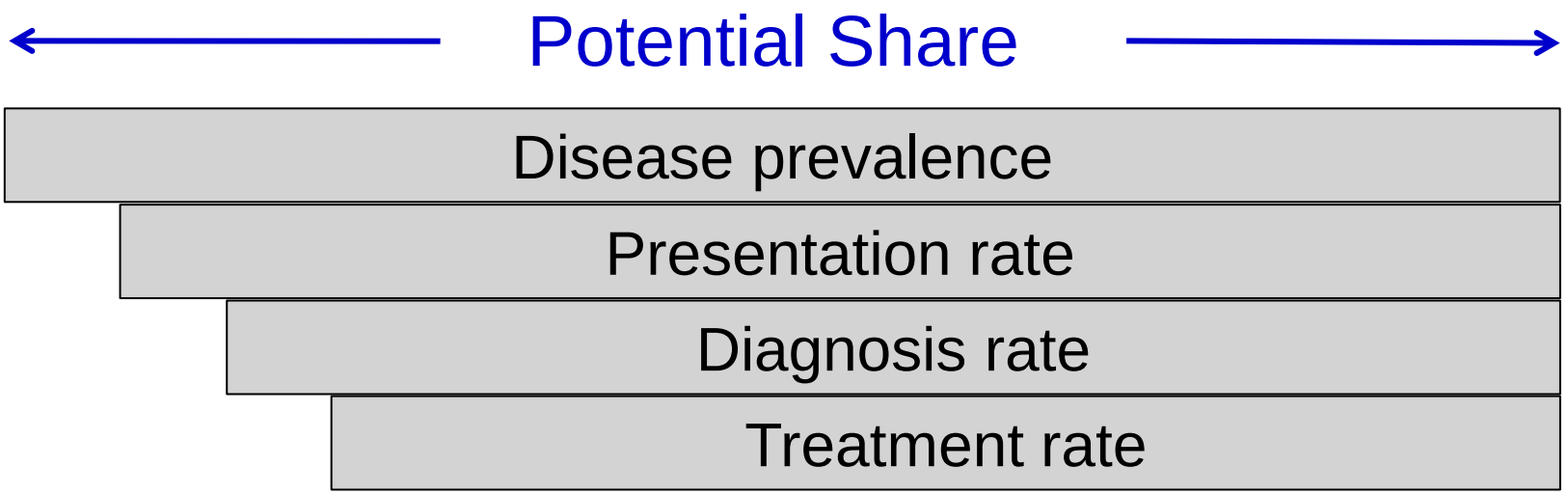
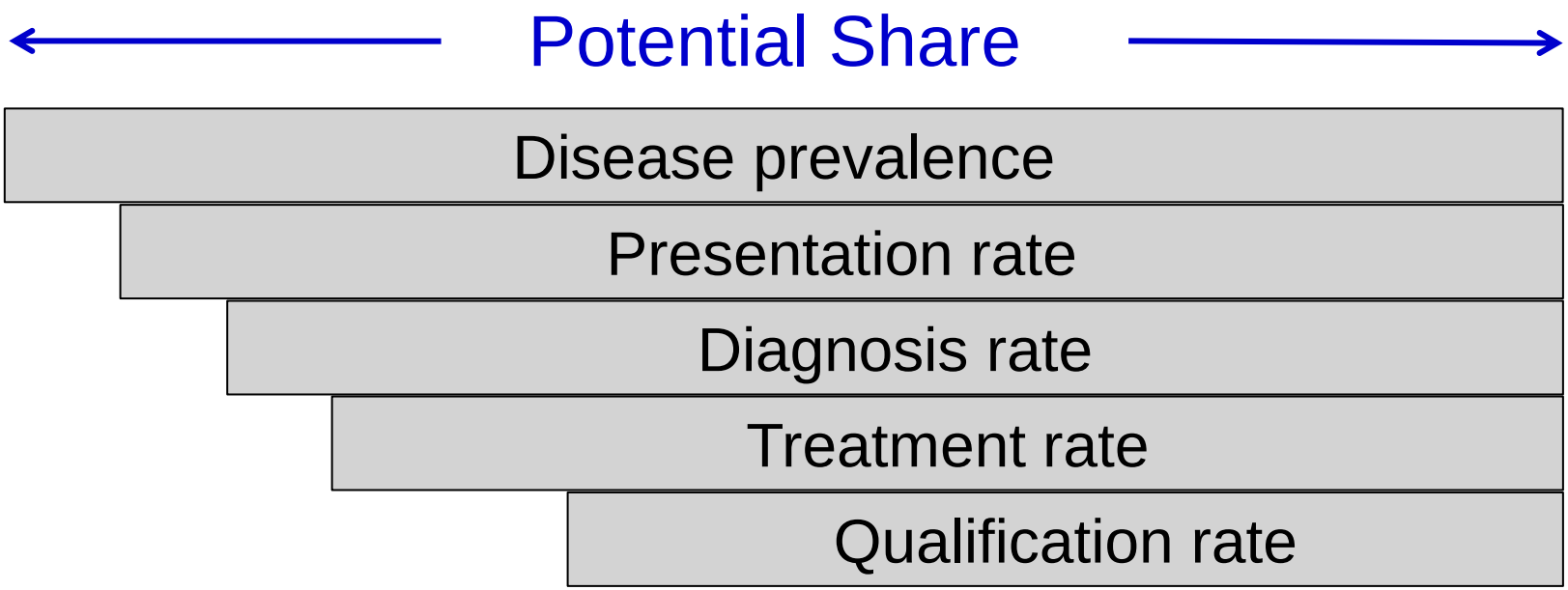
Share of Market Potential



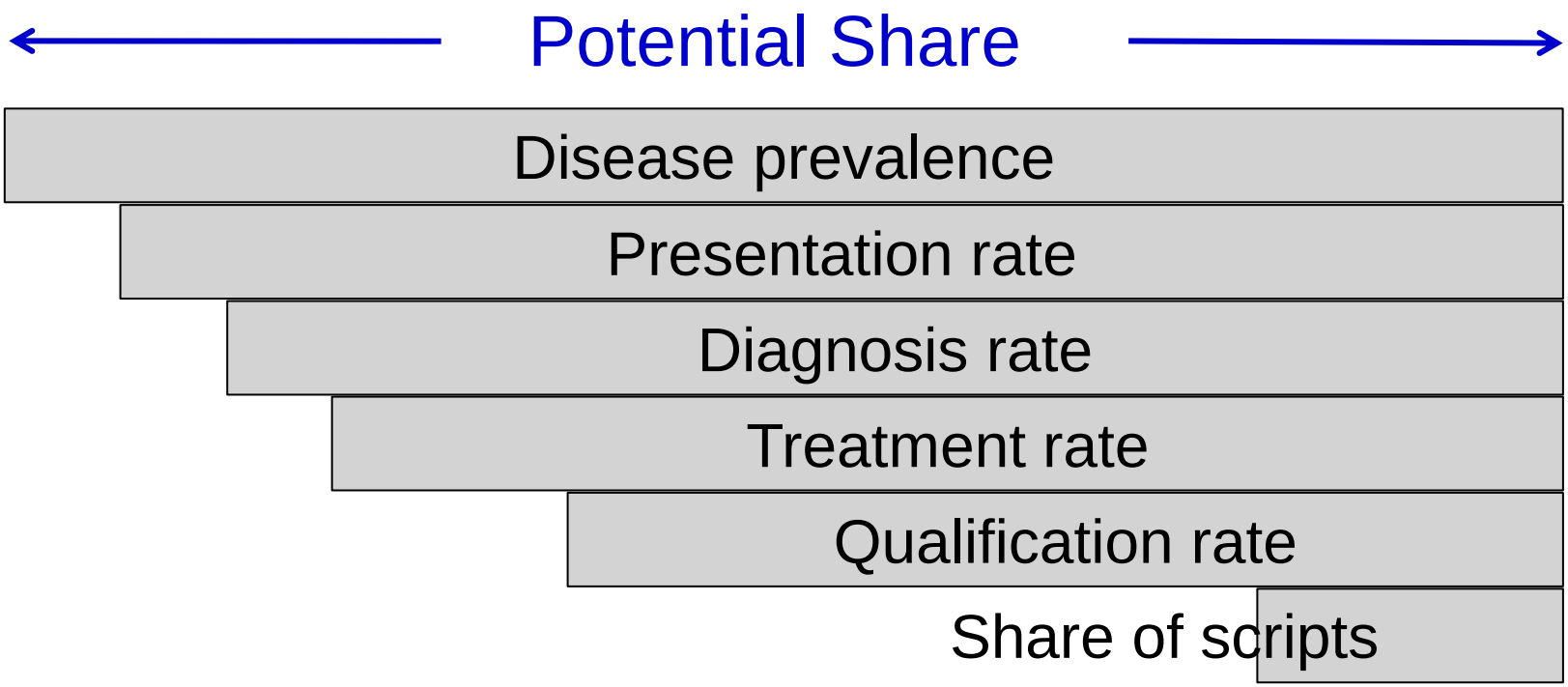
Share of Market Potential



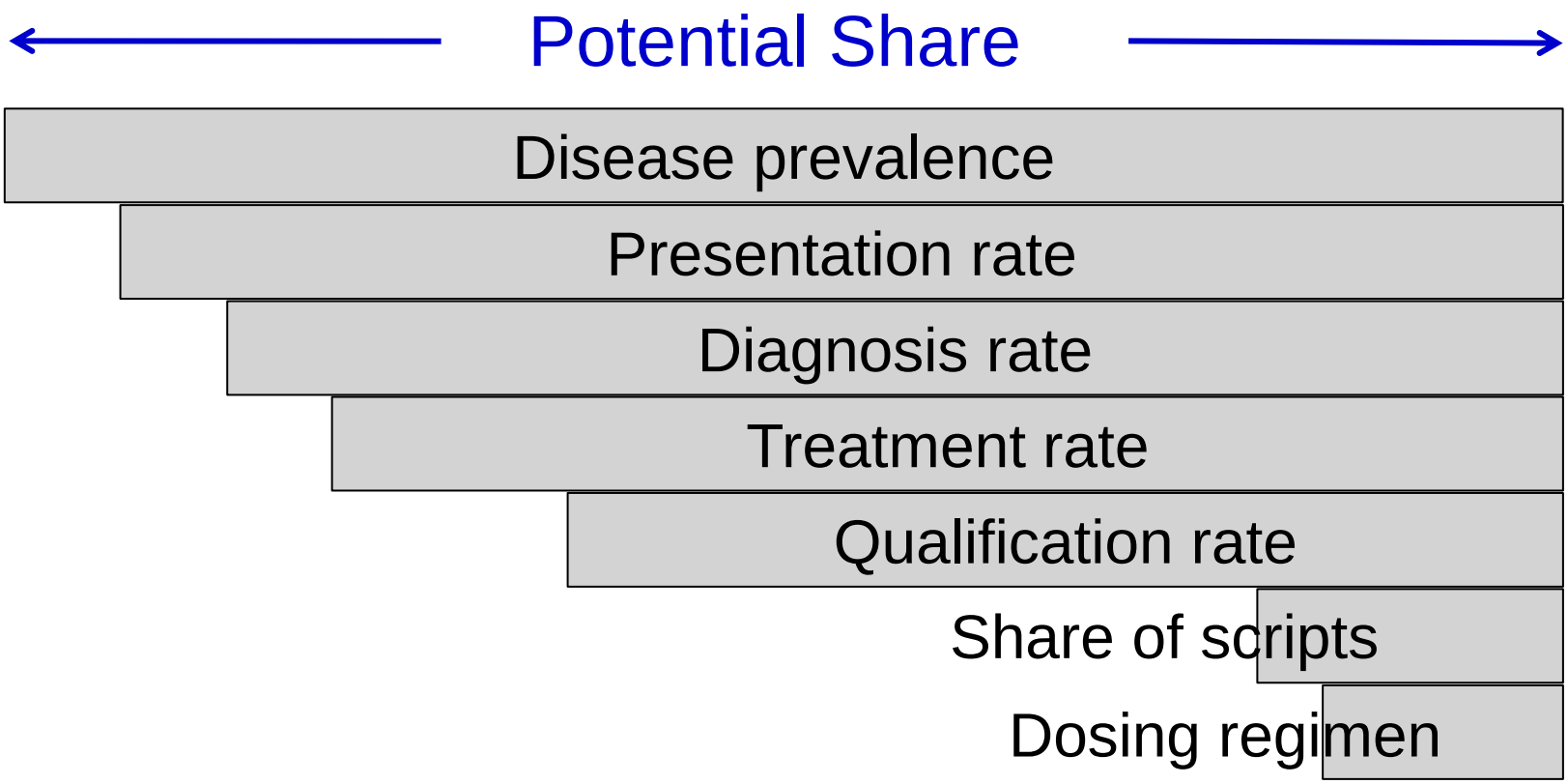
Share of Market Potential



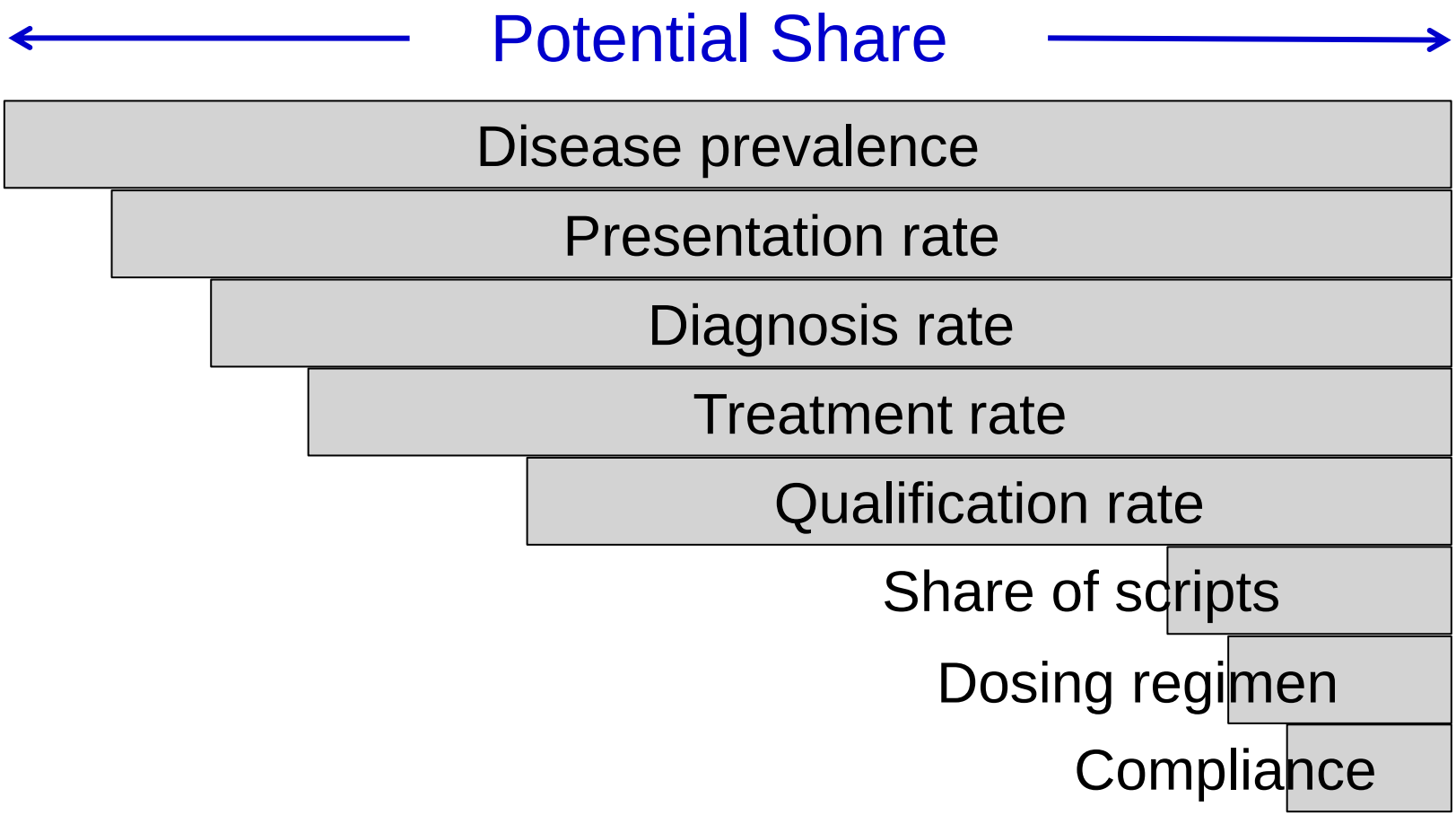
Share of Market Potential



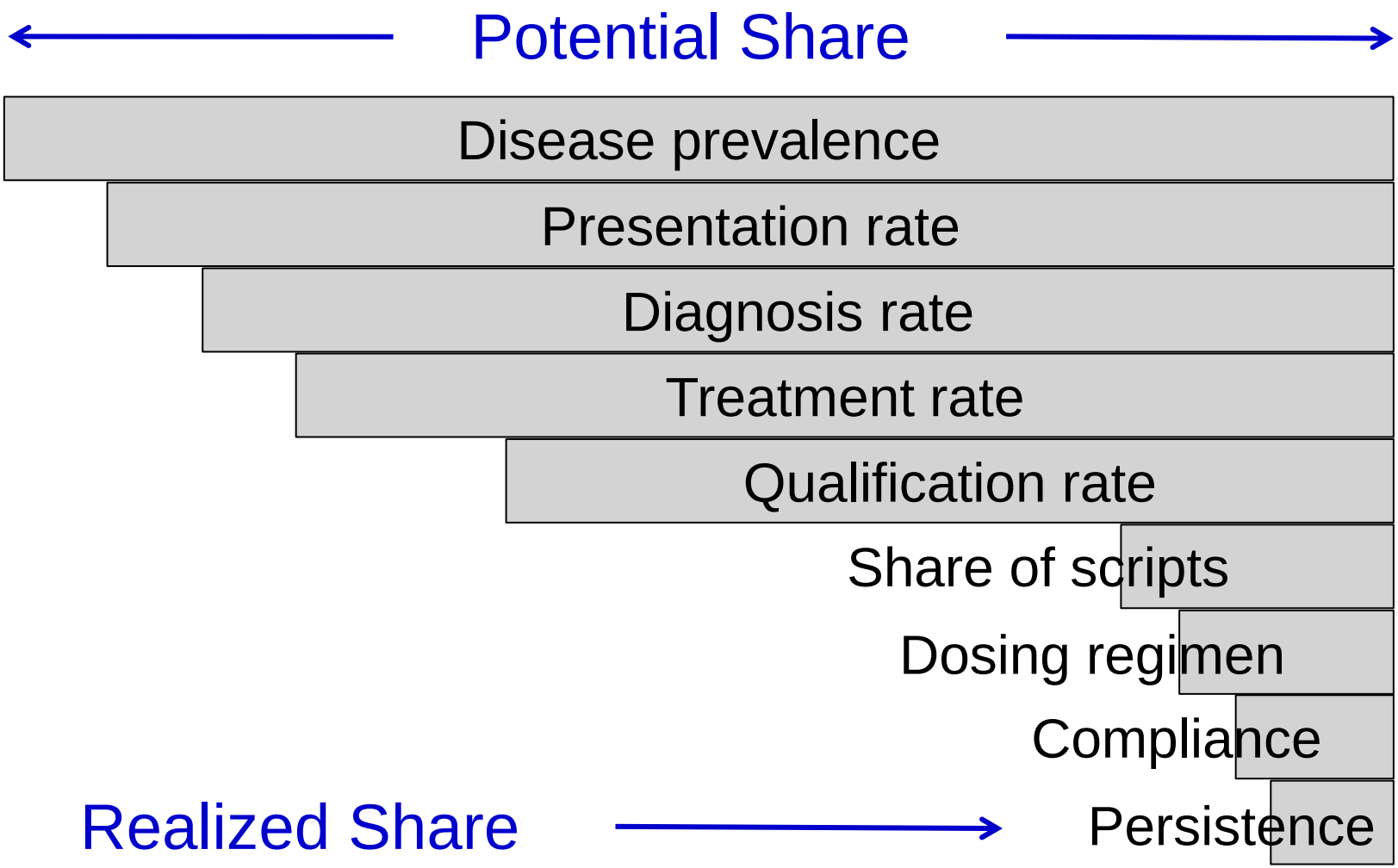
Share of Market Potential



Share of Market Potential



Share of Market Potential



Reconciling Market and Patient Basis

Expected usage based on treatable population

≠

Usage based on audited sales data

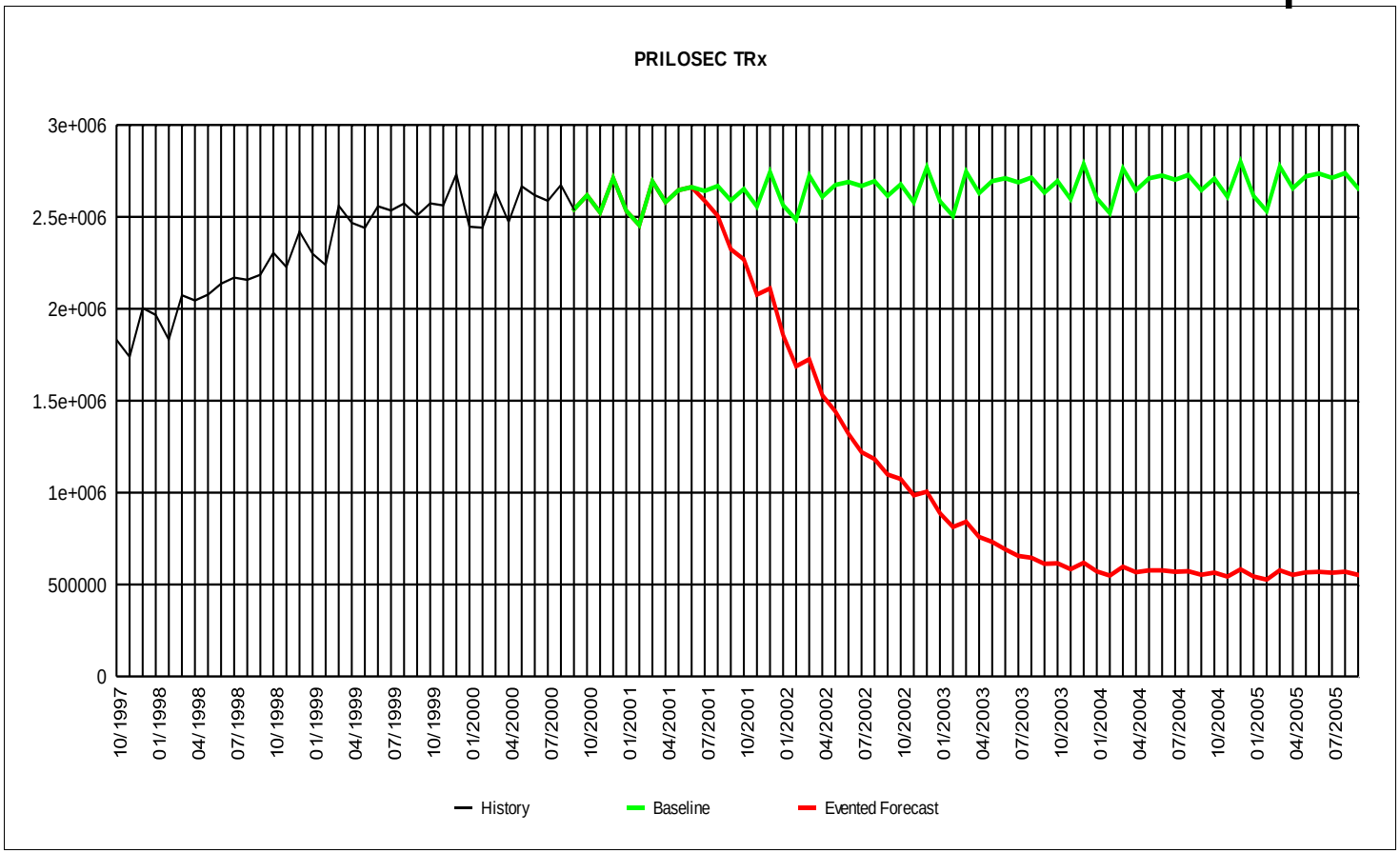
- Possible causes
  - Inaccurate epidemiology data
  - Miscalculated patient flow
  - Misunderstood usage
  - Inaccurate sales audit data
  - Wrong sales audit data pulled

Trending

- Taking history into account: curve fitting and “eventing” approach to forecasting and use of comparables
  - Curve fitting of historical data using statistical methods
  - “Eventing” of the fitted curve into the future, being informed by historical data on comparable products
  - Data: historical scrip and sales data on product(s) and comparables of interest as well as historical “events” and their impact on the above
  - Sources: IMS or WK data, confidential data from client, public company reports

Trend Breaking

Curve fitted + evented forecast example



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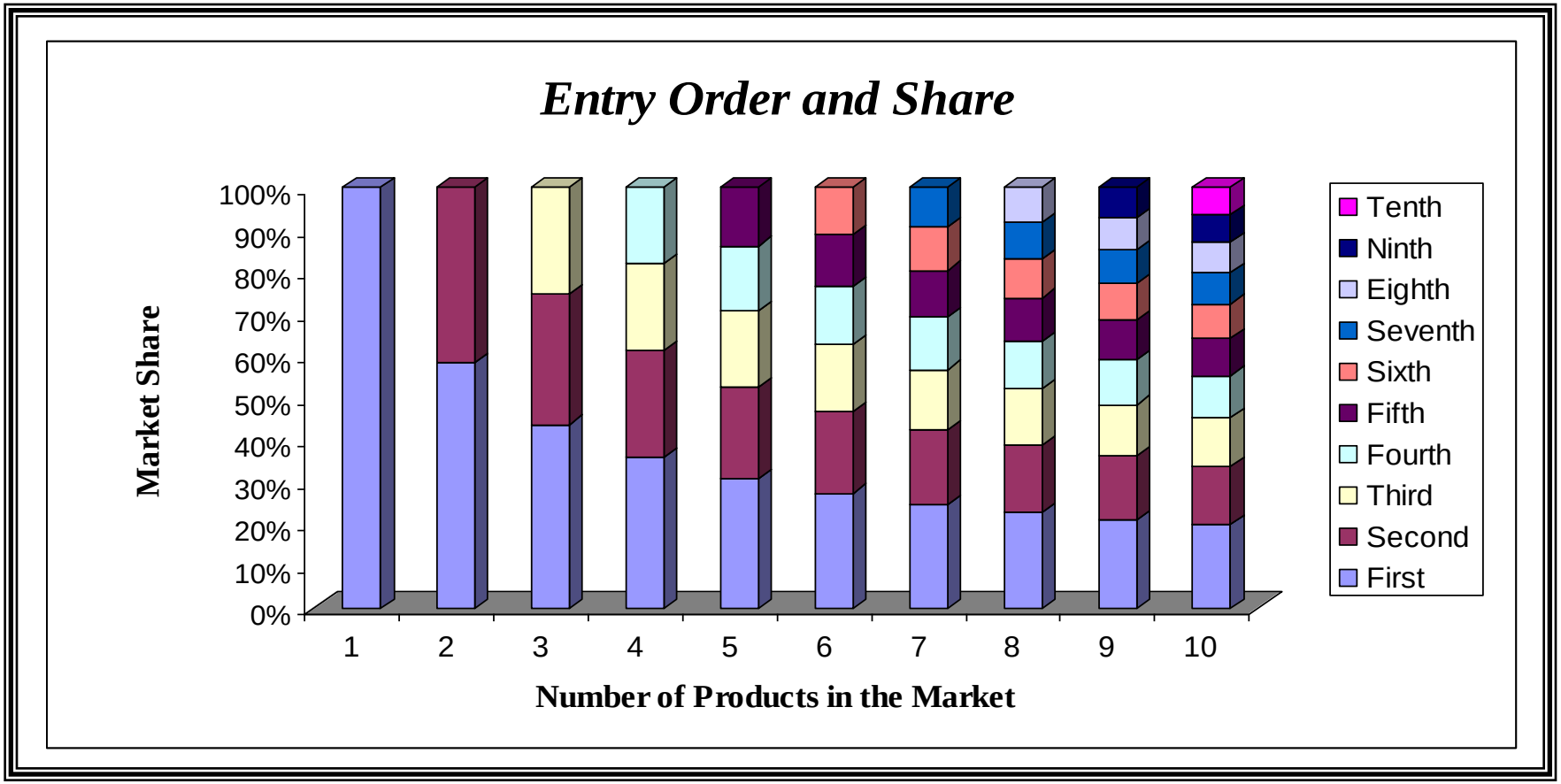
Analogs or Comparables

- The key to “event-based” forecasting is the use of analogs or comparables
- Uses for analogs
  - “Sanity check” peak penetration
  - Fit uptake curve to already forecast peak
  - Affect of generic competition and other IP challenges
  - Pricing and reimbursement outcomes
  - Labeling (product profile) assumptions
- Common variables often sought in analogs:
  - Same indication, therapeutic area
  - Similar product profile (efficacy, safety, administration, dosing)
  - Same physician subgroup
  - Similar marketing strategy (e.g. PCP, hospital, DTC)

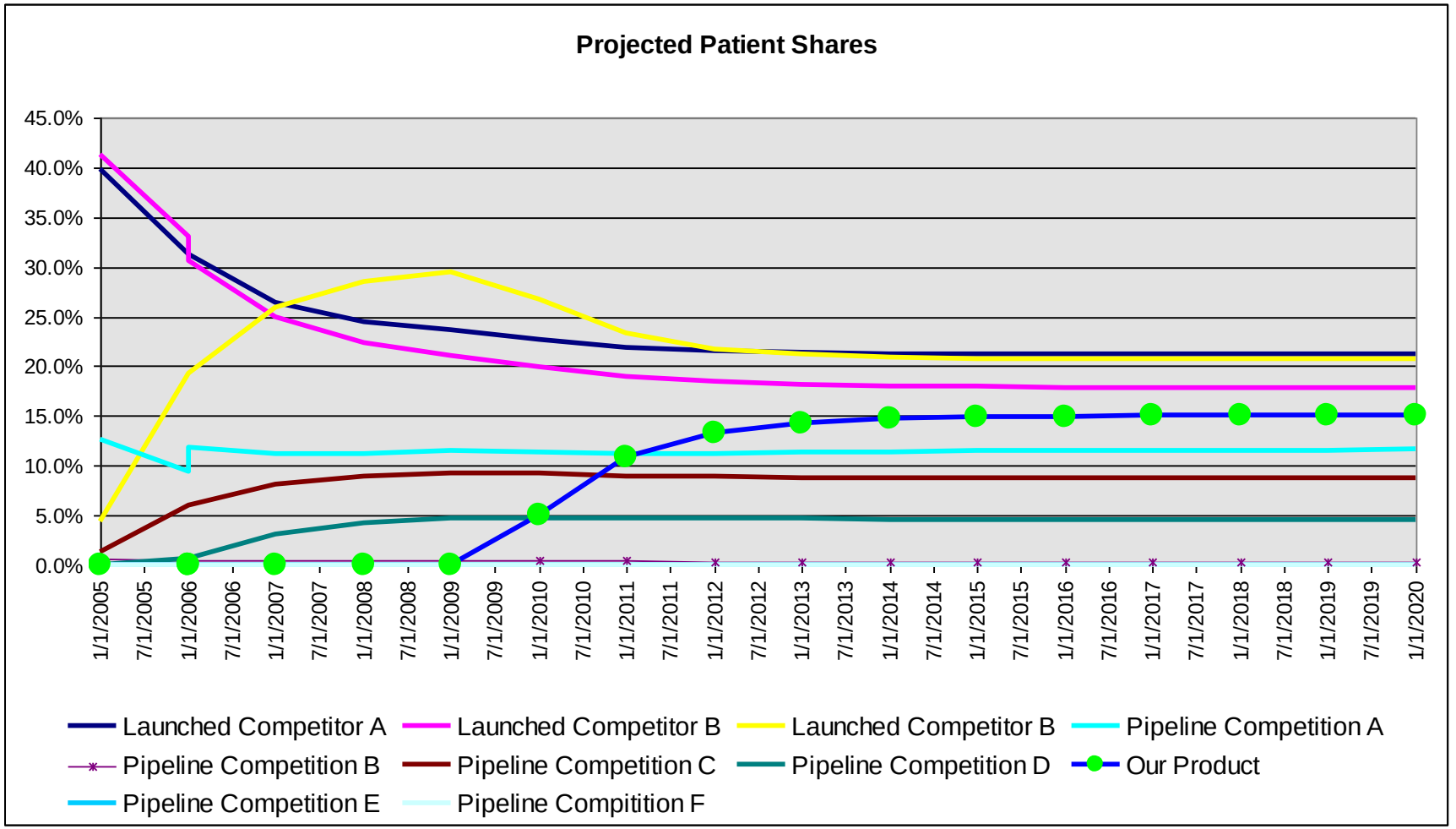
Competitive Analysis

- Competitors can expand a market as well as compete for market share
- Include pipeline products as well as marketed products in competitive analysis
- Major considerations are:
  - Product profile (mechanism of action, efficacy, safety, side effects, dosing)
  - Indications obtained / likely to be obtained; also product label
  - Likelihood of being used 1st line, 2nd line, etc.
  - Clinical unmet need
  - IP strength
  - Pricing / reimbursement
  - Marketer strength
  - Order of entry

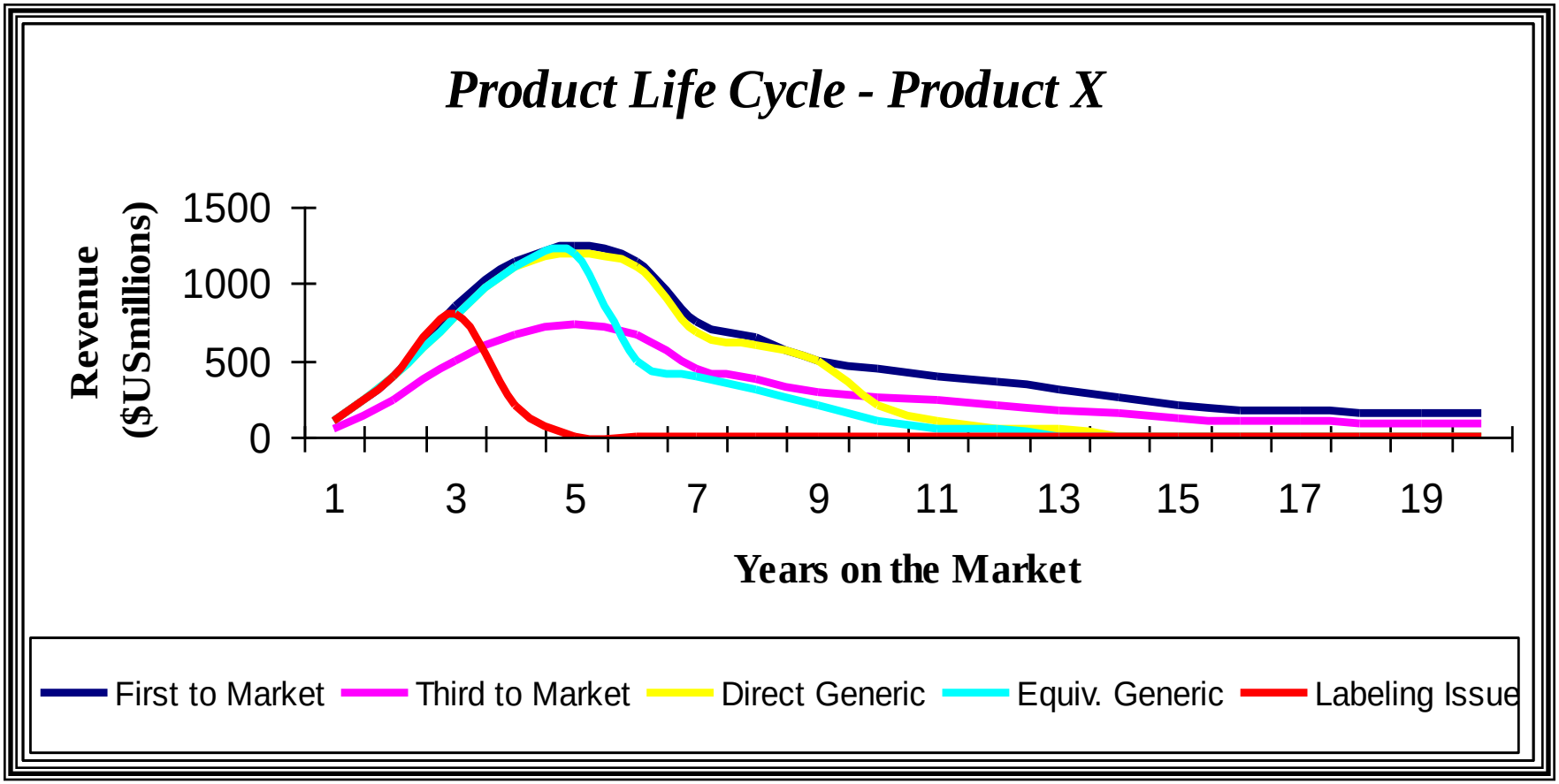
Market Entry Importance



Stealing Matrix in Use



Not All Life Cycles are the Same!



Sensitivity Analysis

Changing one variable at a time:

Price:	$ 2.00	=>	$ 3.00
Rx Share:	4 %	=>	8 %
Discount Rate:	12%	=>	18%

Identifies the impact that different variables have on key financial measures, such as NPV and IRR

Scenario Analysis

Changing multiple variables to establish a “case”

▪ Worst Case:	Price	$ 2.00/tab
	Market Share:	4%
	Discount Rate:	18%
▪ Best Case:	Price	$ 3.00/tab
	Market Share:	8%
	Discount Rate:	12%

Tests your base case assumptions and identifies the range of potential outcomes

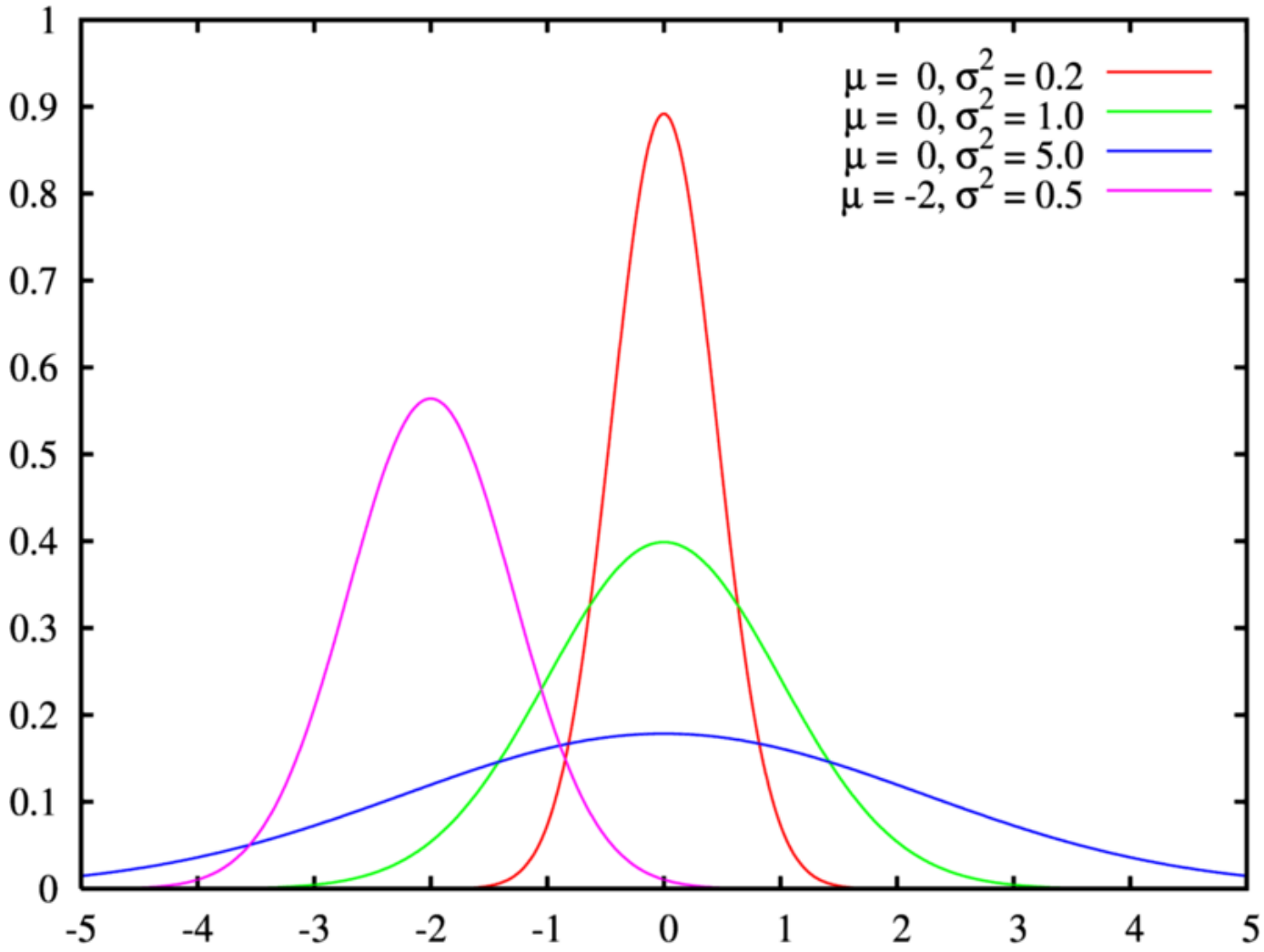
Advanced Simulation Tools – Monte Carlo

- What is it?
  - A procedure that uses a random number generator to create sets of variables from user-specified probability distributions
- How do you do it?
  - Using a software add-on to your spreadsheet program (e.g., *Forecast Architect*® or Crystal Ball):
    1. Specify probability distributions, e.g., mean and standard deviation of a normal distribution, for one or more variables in your forecast
    2. Specify output parameters for your forecast and/or valuation
    3. Run the Monte Carlo simulation

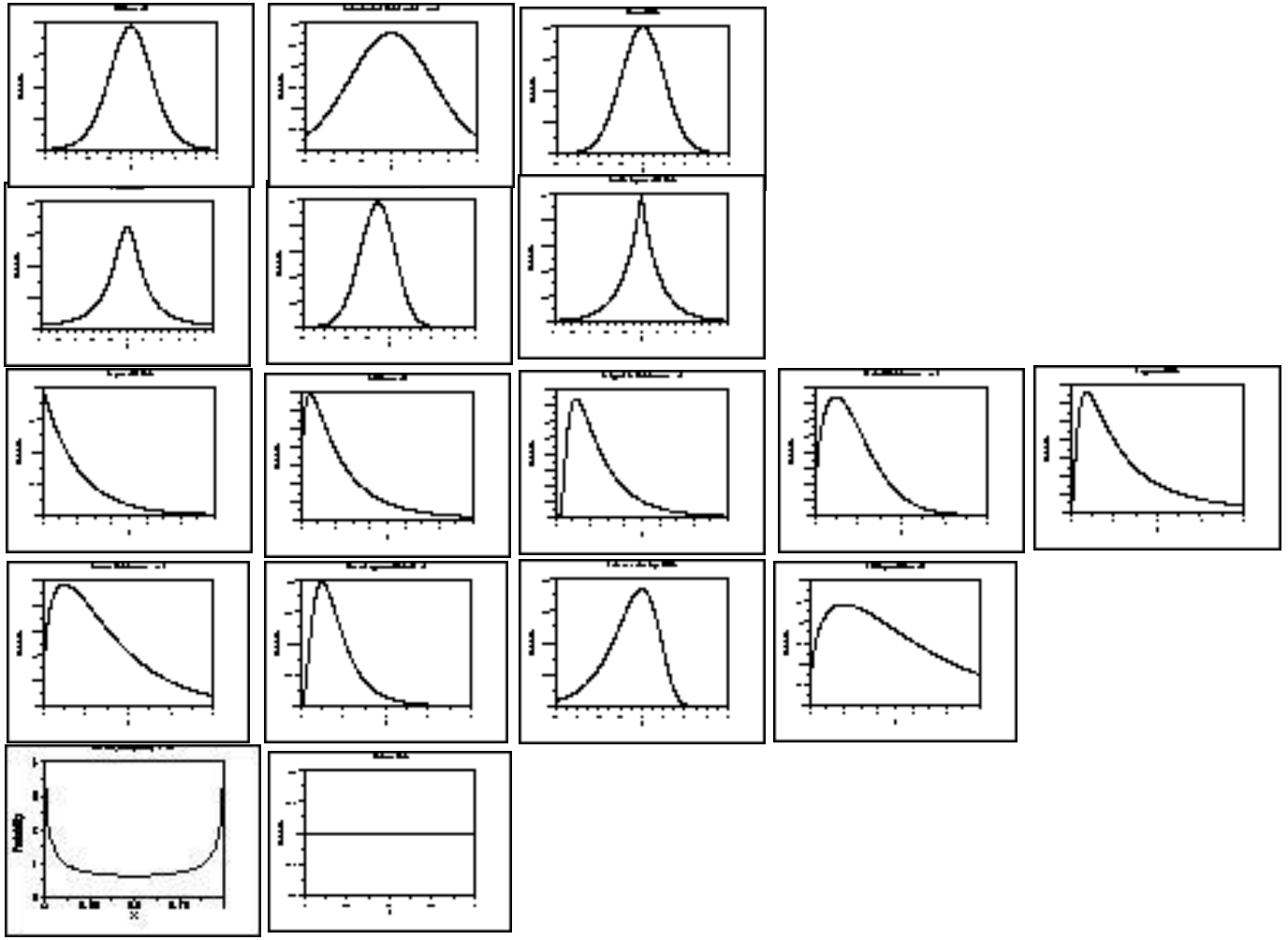
Advanced Simulation Tools – Monte Carlo

- What can you learn from it?
  - Which variables contribute the most to your outputs or results (i.e., sensitivity analysis)?
  - What is the range and distribution of likely outcomes given the variable distributions assigned?
  - What are the major risks and the magnitude of those risks?

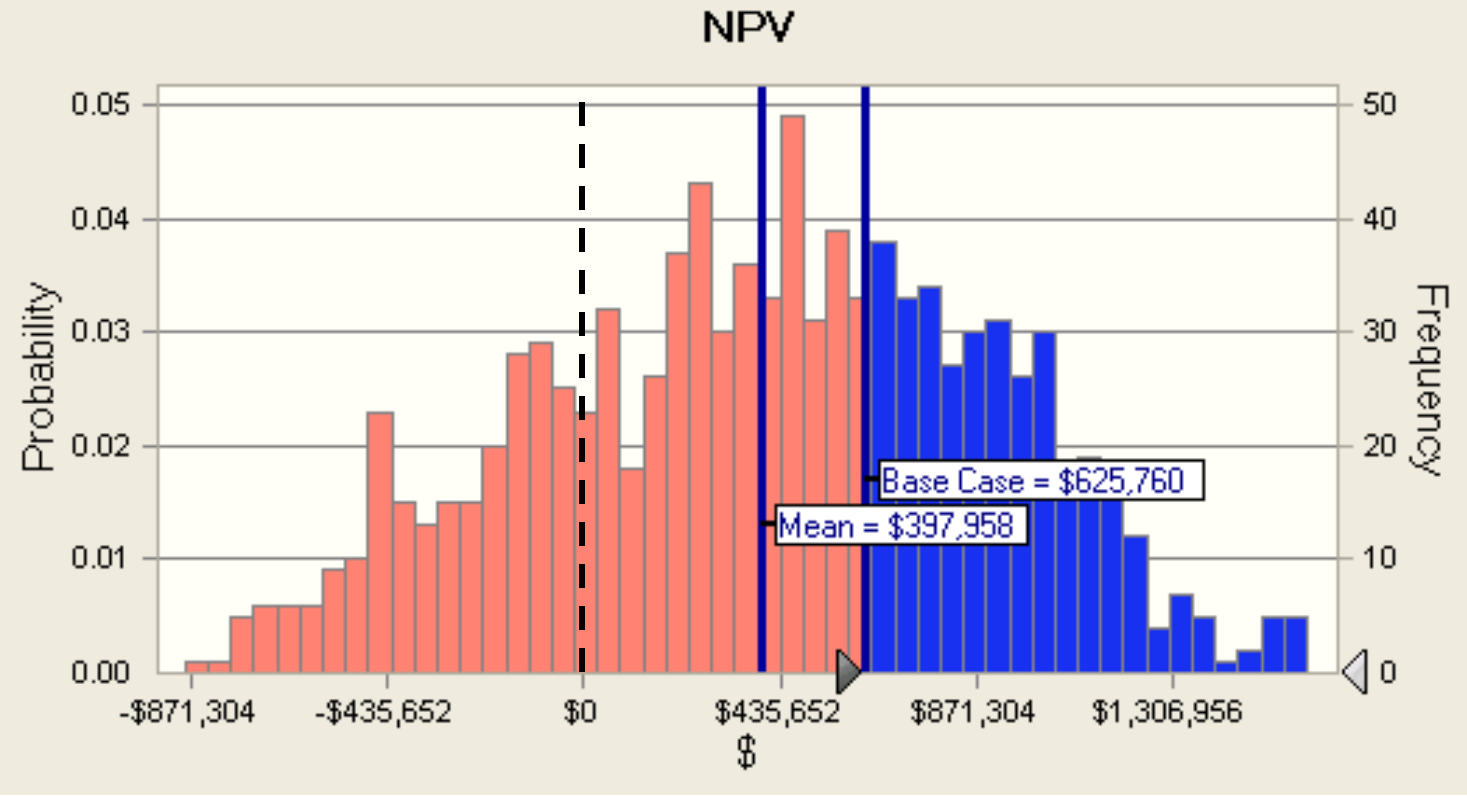
Monte Carlo Distribution Curves



Monte Carlo – A Few More Curves



Monte Carlo Simulation Example



65% probability

35% probability

23.4% probability

76.6% probability

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Monte Carlo Simulation Pros and Cons

Pros

- Relatively inexpensive to evaluate decisions before implementation
- Reveals critical components of the system
- Gives range and probability of results rather than point estimates

Cons

- Results are sensitive to the accuracy of input data
  - One must know variable value ranges and the unique distribution curves
- If you can't model it, you can't use Crystal Ball to simulate it
- Does not provide easy answers to complex problems

Case Study Work and Break!

(return at 4:00pm)

Today's Program

08:30	**Valuation Concepts and Discounted Cash Flow Models**
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17:00	**Close**

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The Art of the Deal

- The good deal results in an arrangement where both parties share in the value created in such a way that each is motivated to maximize that value.
- Pharmaceutical deal value is made up of two basic components
  - Value of the technology
  - Value of the ability generate positive cash flows by commercializing or otherwise applying the technology
- Pharmaceutical deals often span many years with multiple gambles, bets and payoffs to be shared by the partners.

It's not just the math!

Value Sharing Considerations

- Determine the needs / goals of your company and your partner's
  - Current cash position
    - Payouts may be designed to match needs
  - Earnings requirements
    - Consider accretion, gap filling, etc.
  - Hurdle rate
    - Can make a huge valuation difference
  - Corporate Development Goals
    - Franchise development
    - Expertise development
  - Investment goals of stakeholders

Know your partner well

Deal Terms Examples

- Up-front payments
  - Lump-sum
  - Prepaid royalties
  - Direct R&D re-funding
- R&D expense subsidies
- Milestone payments
  - Development
  - Commercial
- Running royalties
  - Fixed % of sales
  - Graduated royalty % based on volume
  - Variable royalty % to account for rights and contingencies
  - Definition of a royalty base (e.g., reach-through royalties, stacking)
- Manufacturing payments
  - Cost plus mark-up
  - % of resale price

Deal Terms Examples (continued)

- Equity and/or Debt Investment
  - At fair market value market
  - For a premium to fair market value
  - Contingent value rights and staged share purchases based on contingent value
- Tactical and Strategic Partnering
  - Profit splitting
  - Shared commercialization rights
  - Shared development rights
  - Transferring commercial resources
  - Transferring R&D resources
  - Planned merger, acquisition or other strategic initiative
- Related or Unrelated Asset Partnering
  - Quids
  - Technology platforms leverage
  - Follow-on technology rights

Limited only by creativity

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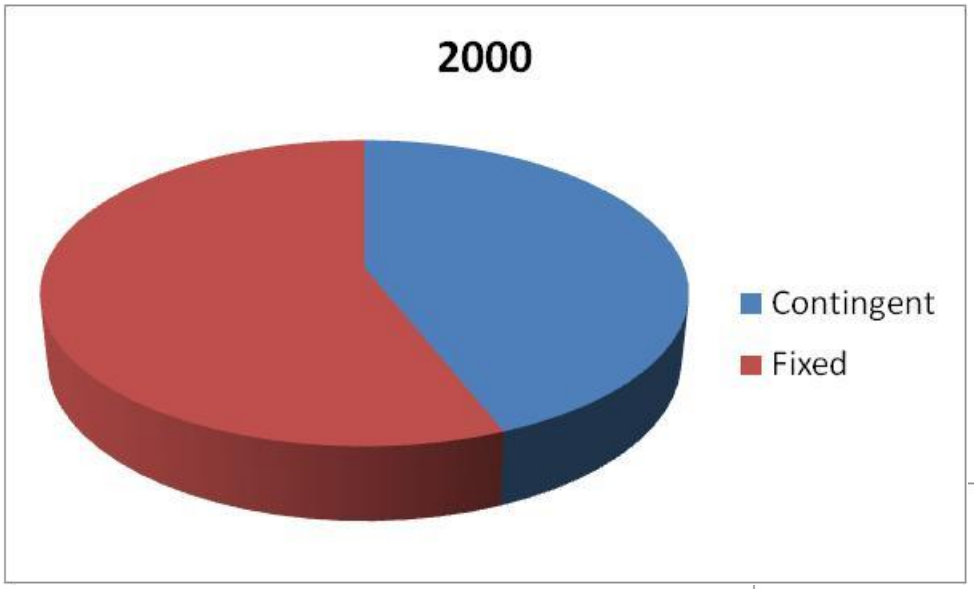
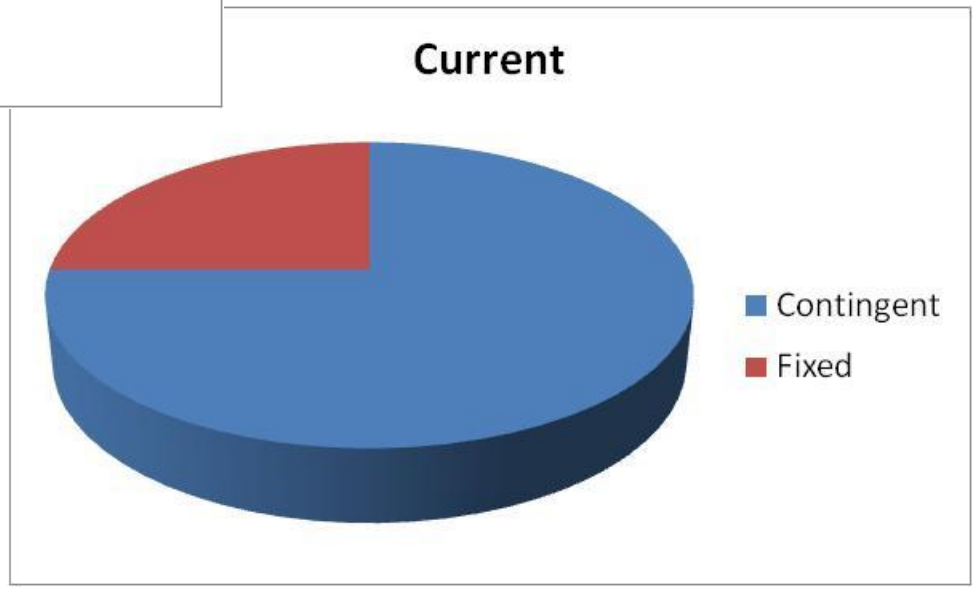
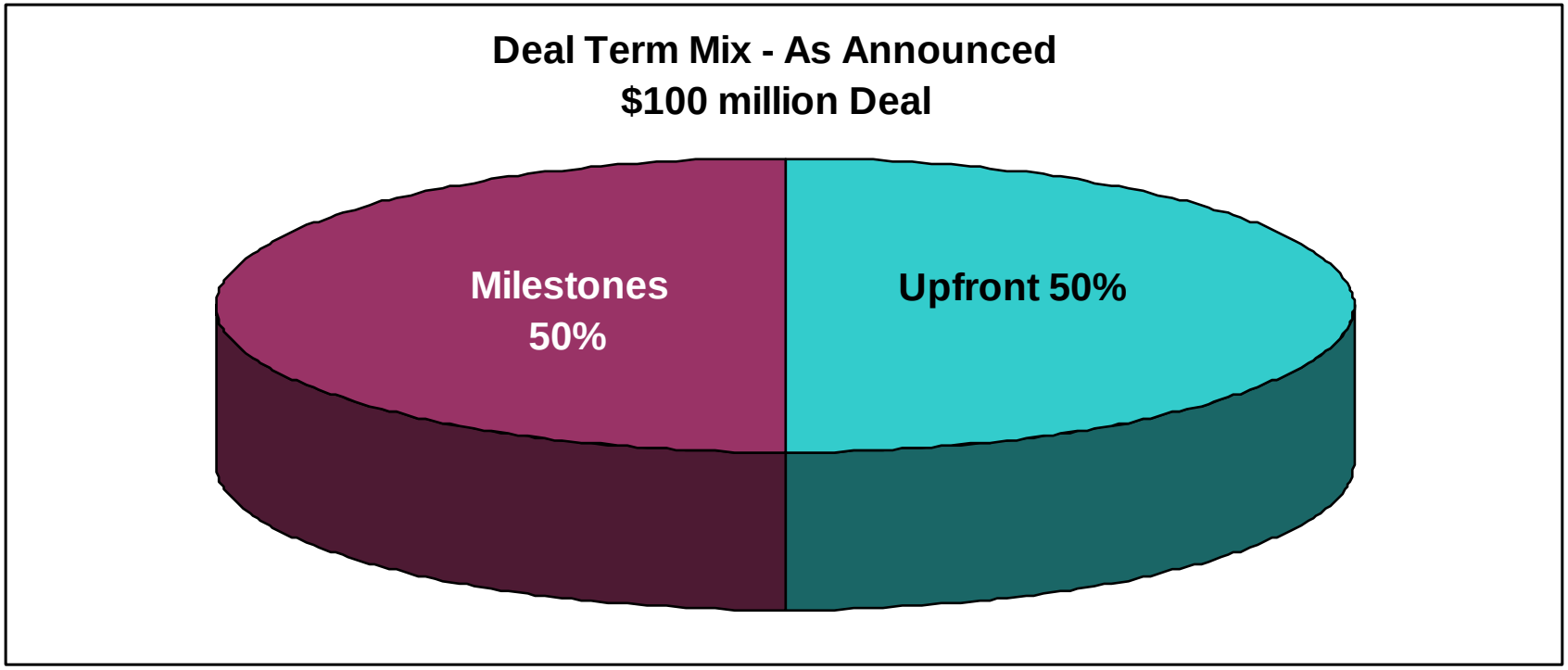
Identifying Comparables





Careful Using Comparables



$100 million? When? How? What-if?

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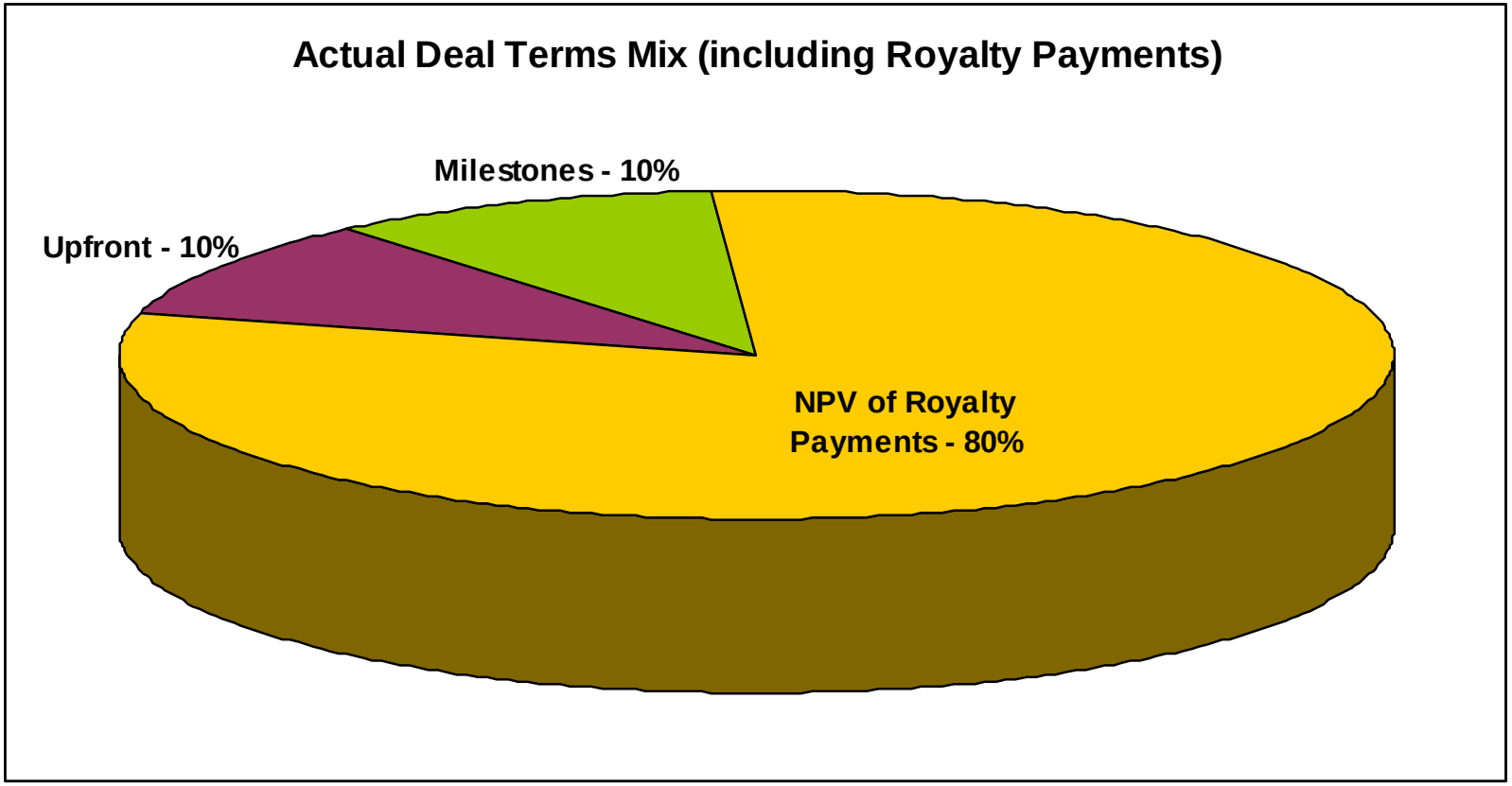
Careful Using Comparables



A different perspective!

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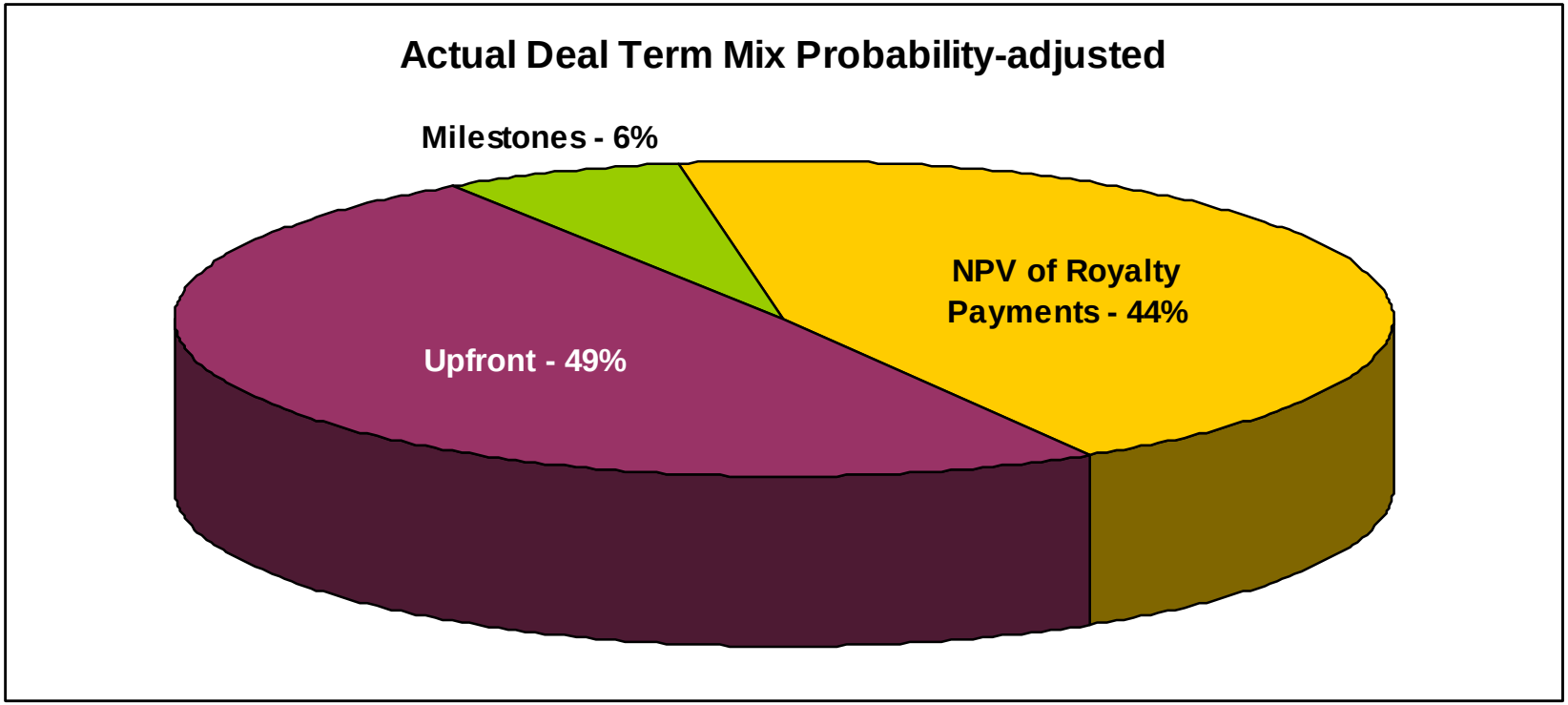
Careful Using Comparables



Getting Clearer?

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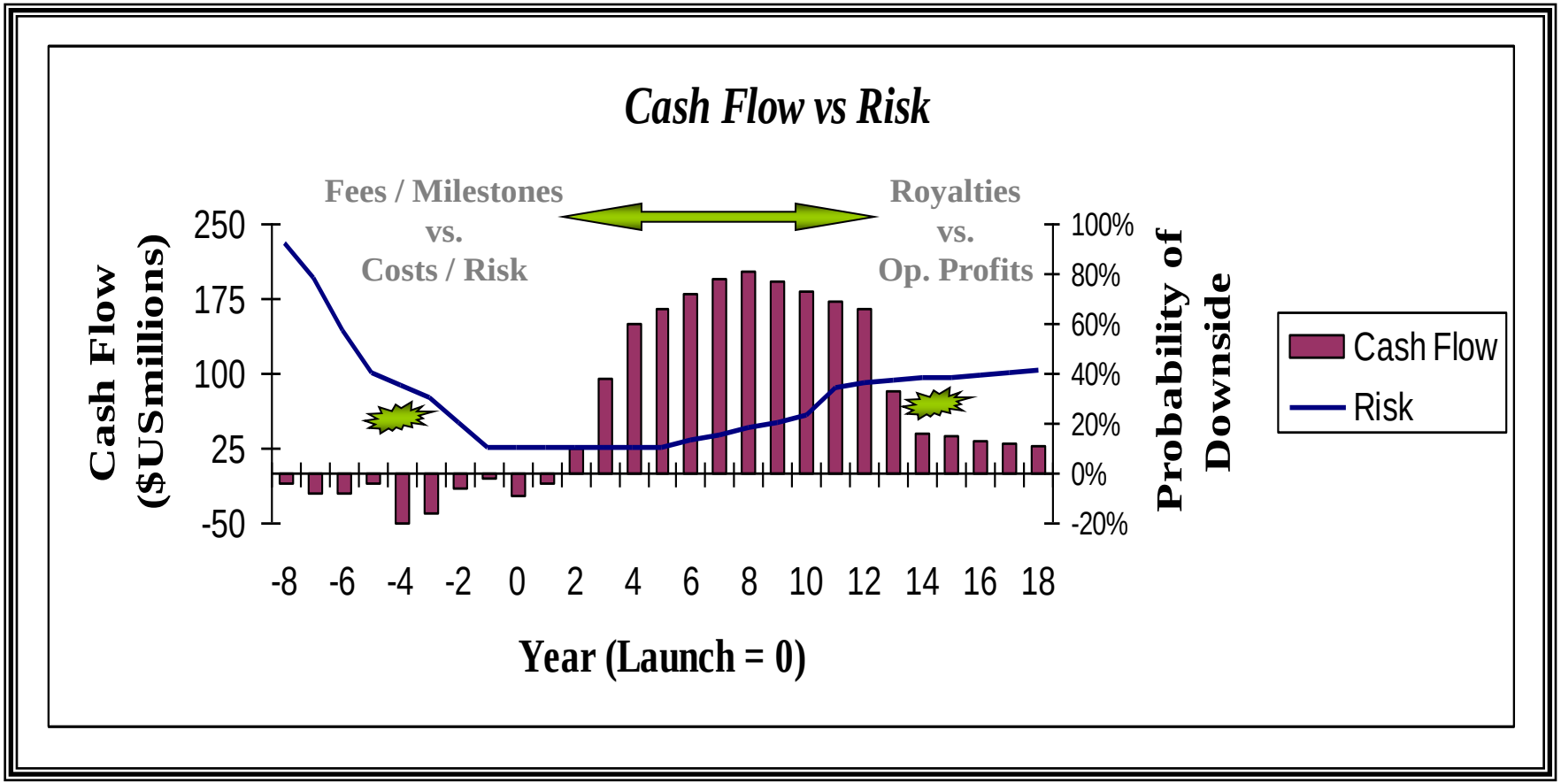
How Much to Pay and Deal Structuring?



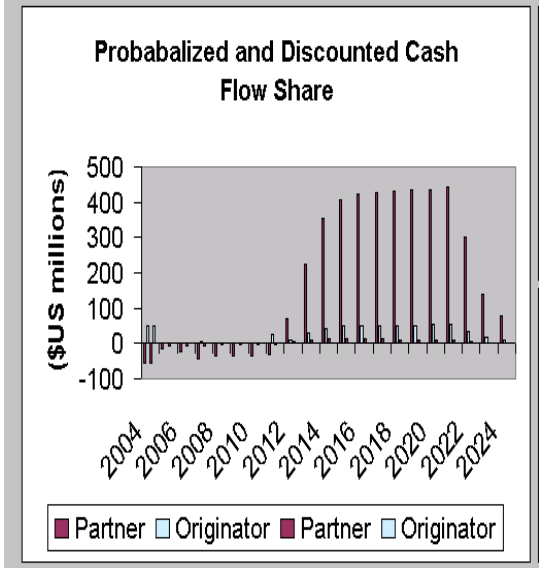
Example Deal

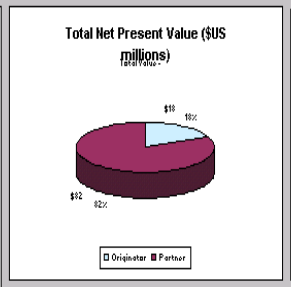
Drug Candidate Licensing Deal

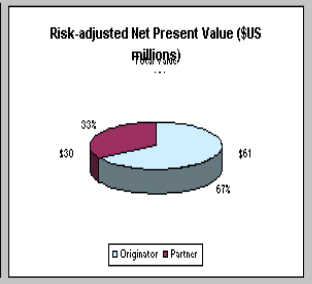
- Opportunity:
  - Stage of Development — Pre-clinical
  - Probability of Launch — 11%
  - R&D — $284 Million
  - Launch Year — 2012
  - Forecast Peak Net Sales — $808 million
- ***Proposed*** Deal:
  - Licensor (Partner) pays R&D
  - Fees and Milestones
    - Upfront — $50 million
    - Enter Phase III — $10 million
    - Launch — $40 million
  - Royalty — 10%

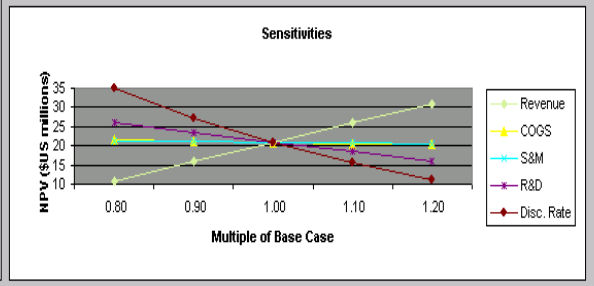
Forecast and Deal Structure Control Panel

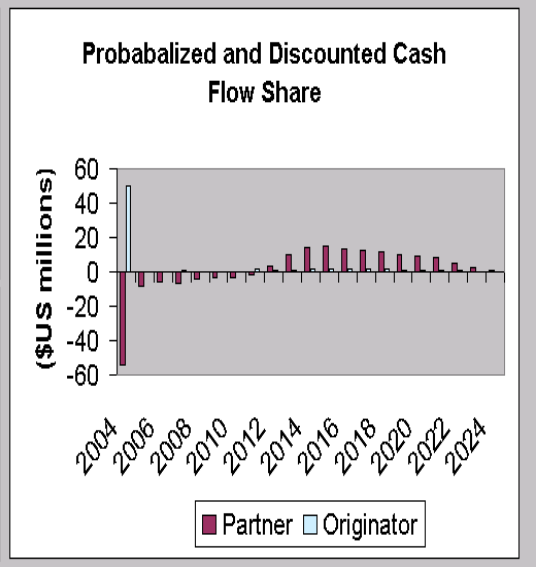
Real Discount Rate	10.82%	*Royalty Scheme*			*Scenario Multiples:*			*Scenario*		*Milestones*		
Nominal Discount Rate	13.40%				Sales	1.20	☑			Upfront Fee	50.00	☑
Inflation Factor	1.00	Range 1	10%	0	Cost of Goods Sold	1.00		One		United States IND Approval	0.00	
Marginal Tax Rate	34.0%	Range 2	10%	250	Sales & Marketing	1.00		Two		Initiation of Phase III trials	10.00	☑
Working Capital as % Revenue	-15.0%	Range 3	10%	500	Research & Development	1.00		Three		United States NDA approval	50.00	☑
Terminal Value Growth Rate	-5.0%				Other Operating Expenses	1.00		Four		Cummulative revenue of $1 billion in US	0.00	











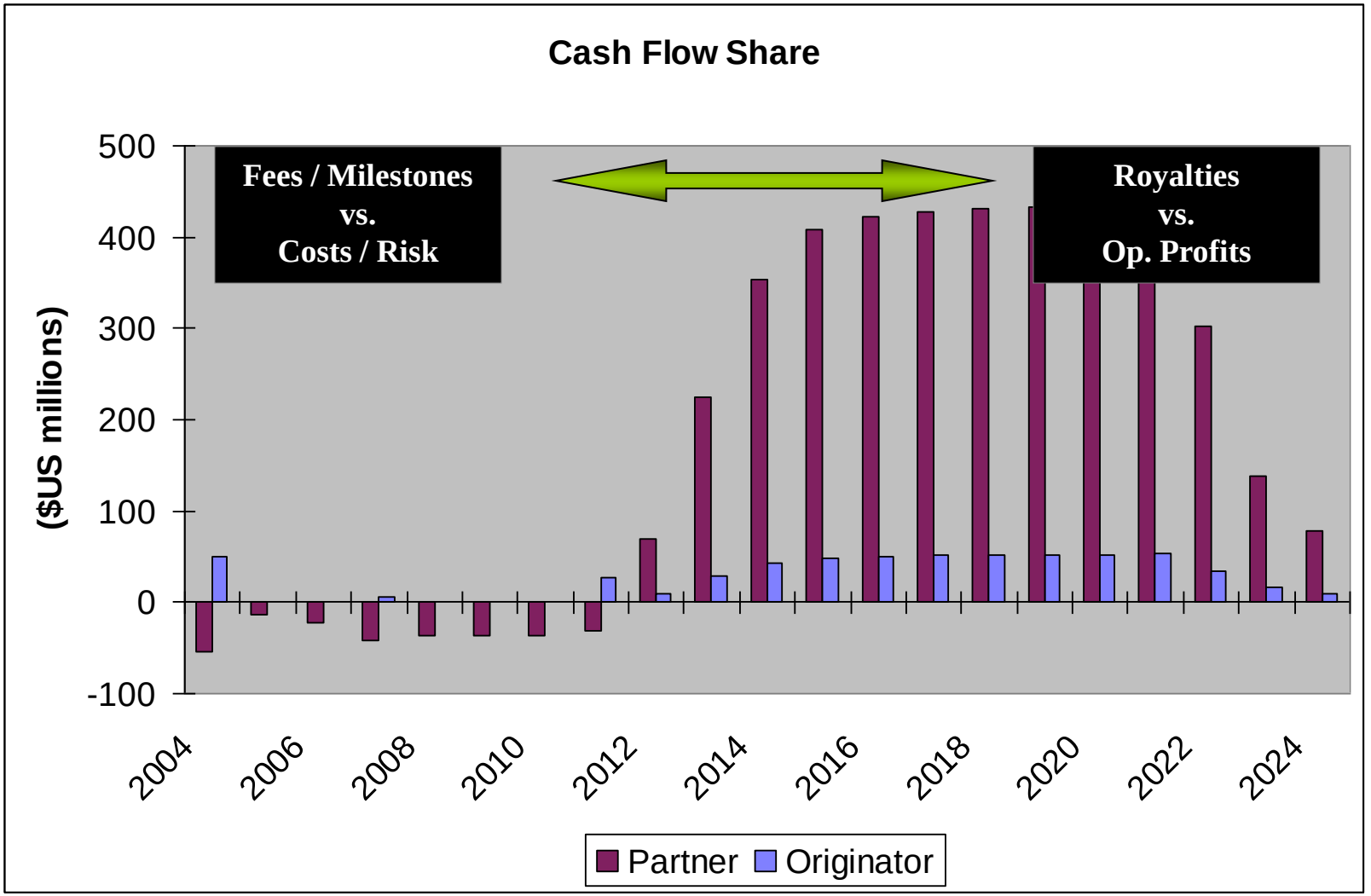
Total Product Value					Value to Originator					Value to Partner				
Value Components	Consolidated	Area			Value Components	Consolidated	Area			Value Components	Consolidated	Area		
		United States	Major Europe	Canada			United States	Major Europe	Canada			United States	Major Europe	Canada
NPV without Terminal Value	953.1	627.7	282.7	42.7	NPV without Terminal Value	176.3	119.3	49.2	7.8	NPV without Terminal Value	776.7	508.4	233.4	34.9
NPV of Terminal Value	48.4	33.0	13.3	2.1	NPV of Terminal Value	5.2	3.5	1.5	0.2	NPV of Terminal Value	43.2	29.4	11.9	1.9
Terminal Value as % Total NPV	4.8%	5.0%	4.5%	4.7%	Terminal Value as % Total NPV	2.9%	2.9%	2.9%	2.9%	Terminal Value as % Total NPV	5.3%	5.5%	4.8%	5.1%
Total NPV	**1,001.5**	**660.7**	**296.0**	**44.9**	**Total NPV**	**181.6**	**122.8**	**50.7**	**8.1**	**Total NPV**	**819.9**	**537.8**	**245.3**	**36.8**
Probabilty-Weighted NPV	91.2	58.6	28.4	4.2	Probabilty-Weighted NPV	60.8	37.8	19.7	3.3	Probabilty-Weighted NPV	30.4	20.7	8.7	0.9
					NPV as % of Total NPV	18.1%				NPV as % of Total NPV	81.9%			
					NPV as % of Prob-Weighted NPV	66.7%				NPV as % of Prob-Weighted NPV	33.3%			

Cash Flow Forecast Excerpts

Cash Flow Statement			2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Partner:														
Net Revenue		0.0	-	-	-	-	-	-	-	-	193.1	499.5	704.0	760.9
Royalty			-	-	-	-	-	-	-	-	19.3	49.9	70.4	76.1
Cost of Goods Sold			-	-	-	-	-	-	-	-	8.9	23.1	32.6	35.2
Gross Profit			-	-	-	-	-	-	-	-	164.8	426.4	601.0	649.6
Total Operating Expenses			6.8	20.3	33.8	64.0	54.0	54.0	54.0	46.8	15.4	16.8	17.8	18.0
EBITDA			(6.8)	(20.3)	(33.8)	(64.0)	(54.0)	(54.0)	(54.0)	(46.8)	149.4	409.6	583.3	631.6
Terminal Value (to Partner)	PV =	$43.2	-	-	-	-	-	-	-	-	-	-	-	-
Net Cash Flow - Partner	**NPV =**	**819.9**	**(54.5)**	**(13.4)**	**(22.3)**	**(42.2)**	**(35.6)**	**(35.6)**	**(35.6)**	**(30.9)**	**69.7**	**224.4**	**354.3**	**408.3**
Originator:														
Cash Flows														
Royalty Earned		0.0	-	-	-	-	-	-	-	-	19.3	49.9	70.4	76.1
Research and Development			-	-	-	-	-	-	-	-	-	-	-	-
Sales & Marketing			-	-	-	-	-	-	-	-	-	-	-	-
Taxable Milestones Earned			-	-	-	10.00	-	-	-	40.00	-	-	-	-
Other Expenses (Includes deal costs)			-	-	-	-	-	-	-	-	0.1	0.2	0.4	0.4
Net EBITDA			-	-	-	10.0	-	-	-	40.0	19.2	49.7	70.1	75.7
Capitalized Fees and Costs to Originator			50.0	-	-	-	-	-	-	-	-	-	-	-
Terminal Value	PV =	$5.2	-	-	-	-	-	-	-	-	-	-	-	-
Net Cash Flow - Originator			**50.0**	**-**	**-**	**6.6**	**-**	**-**	**-**	**26.4**	**9.8**	**28.2**	**43.2**	**49.1**
	NPV =	**181.6**												
Product Total:														
Product EBITDA			(6.8)	(20.3)	(33.8)	(54.0)	(54.0)	(54.0)	(54.0)	(6.8)	168.6	459.3	653.3	707.3
Terminal Value	PV =	$48.41	-	-	-	-	-	-	-	-	-	-	-	-
Net Cash Flow - Total Product			**(4.5)**	**(13.4)**	**(22.3)**	**(35.6)**	**(35.6)**	**(35.6)**	**(35.6)**	**(4.5)**	**79.4**	**252.6**	**397.4**	**457.4**
	NPV =	**1,001.5**												

This cash flow was made smaller by hiding some rows and deleting some columns to make the image readable on this slide.

Partner's Cash Flow Timing



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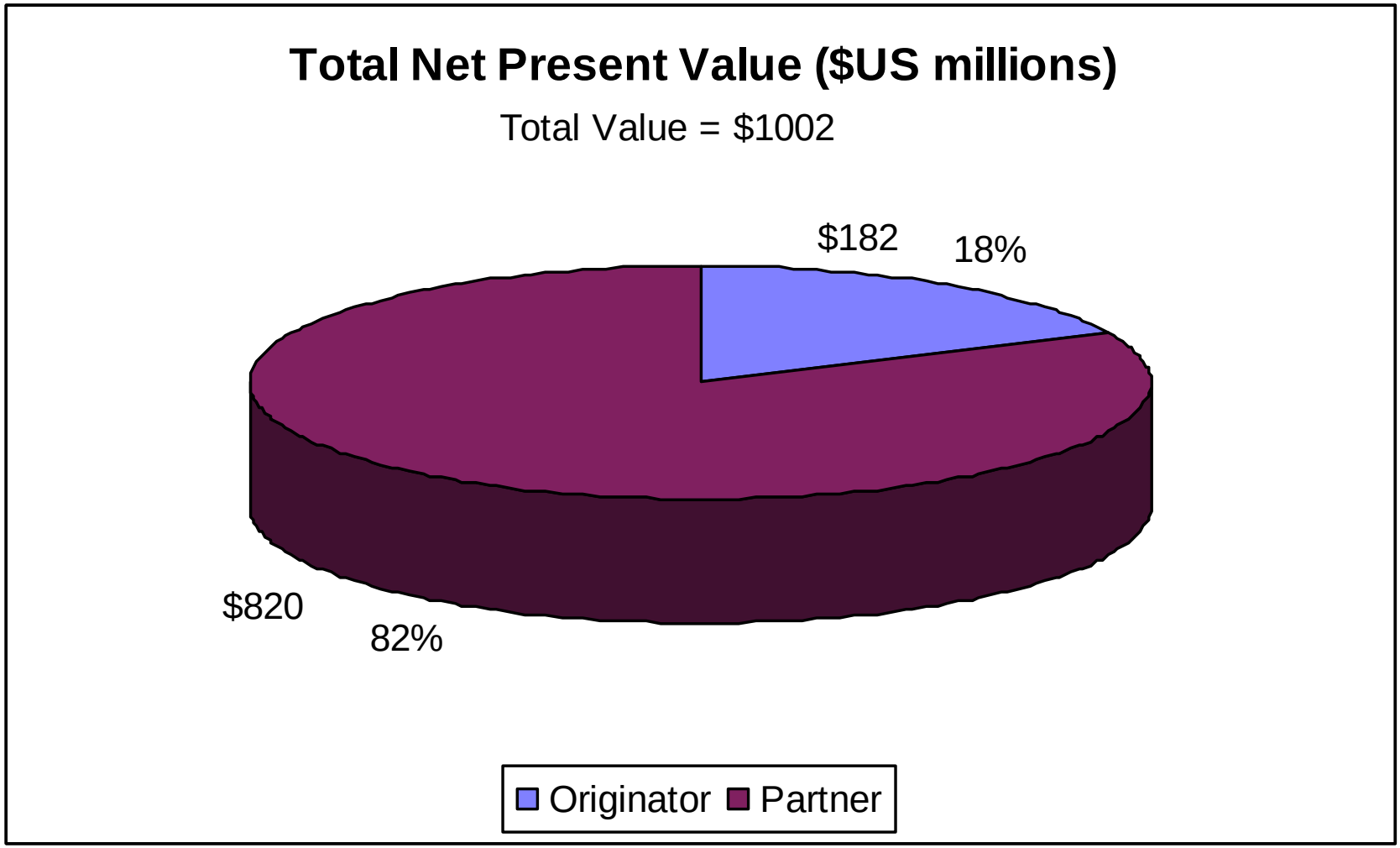
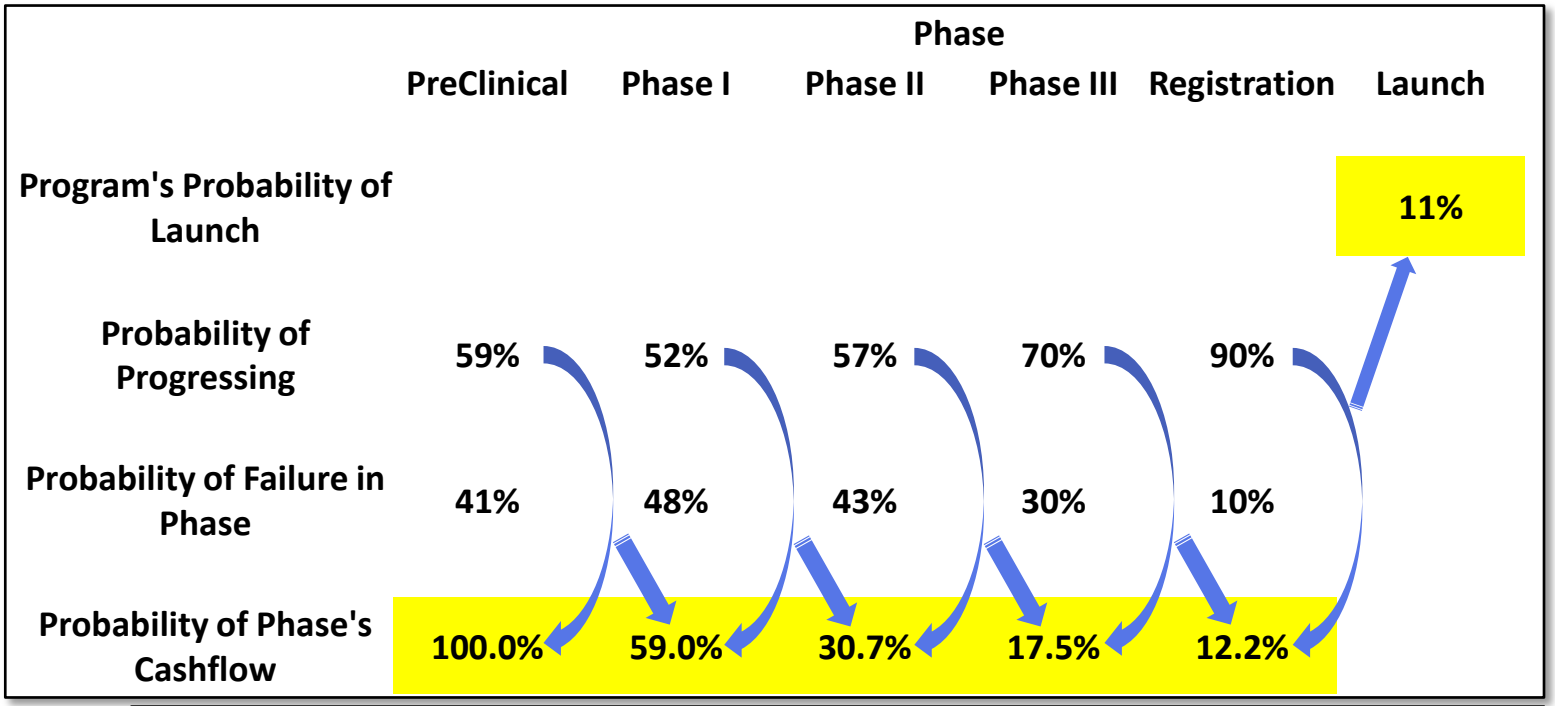
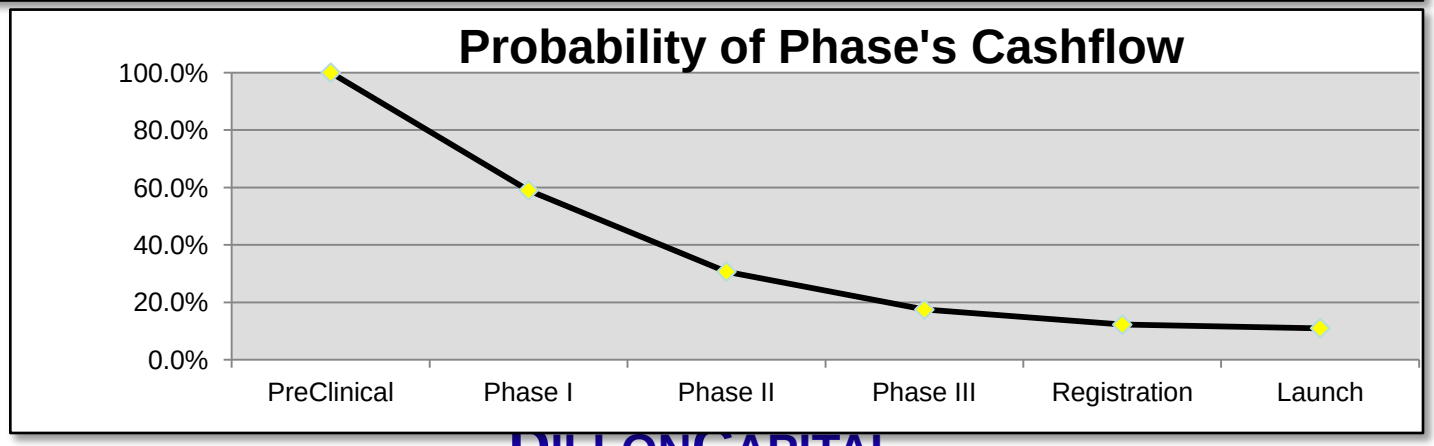
Resulting Shares of the Pie



Investment and Milestone Risk Gaming





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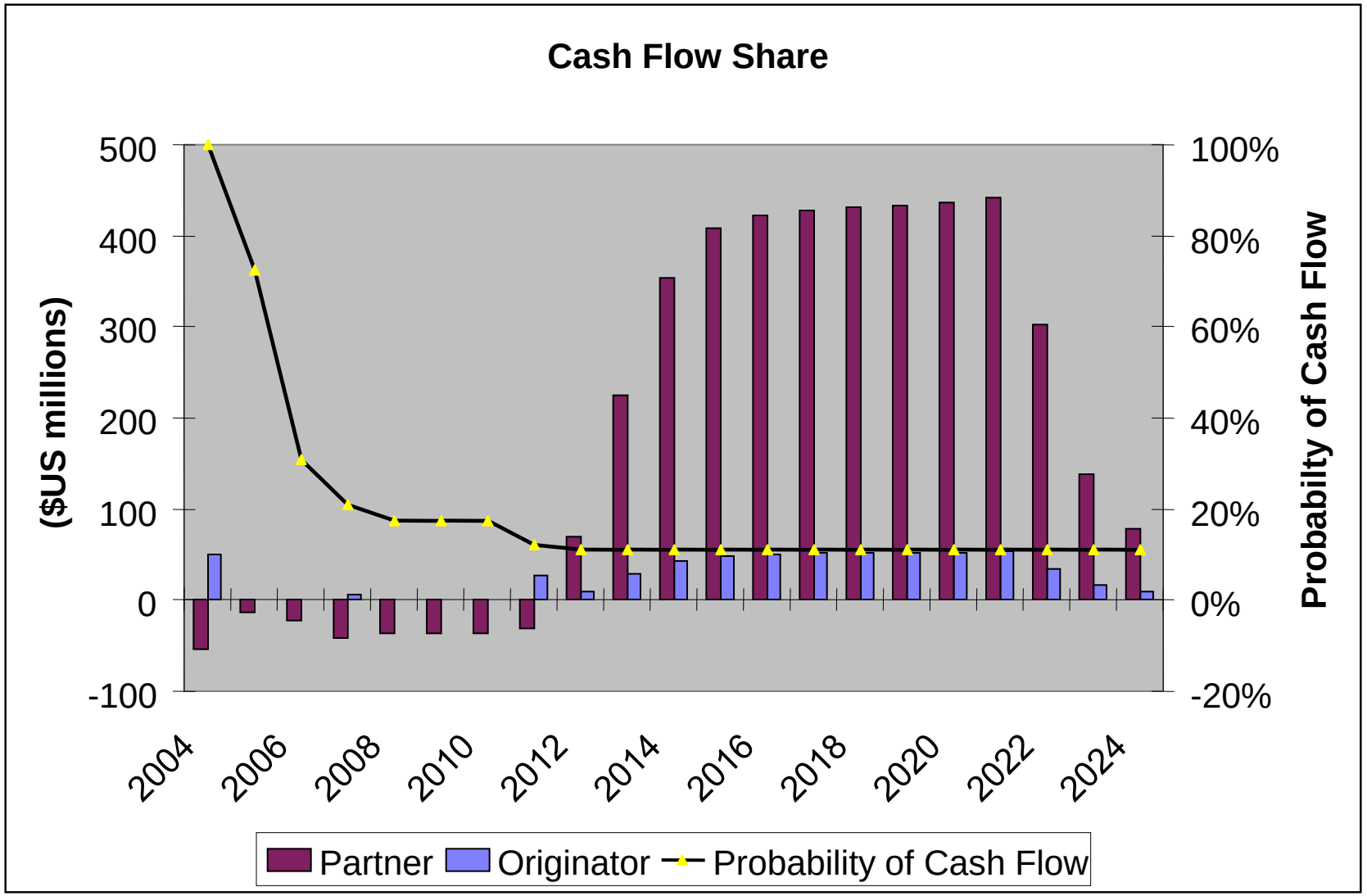
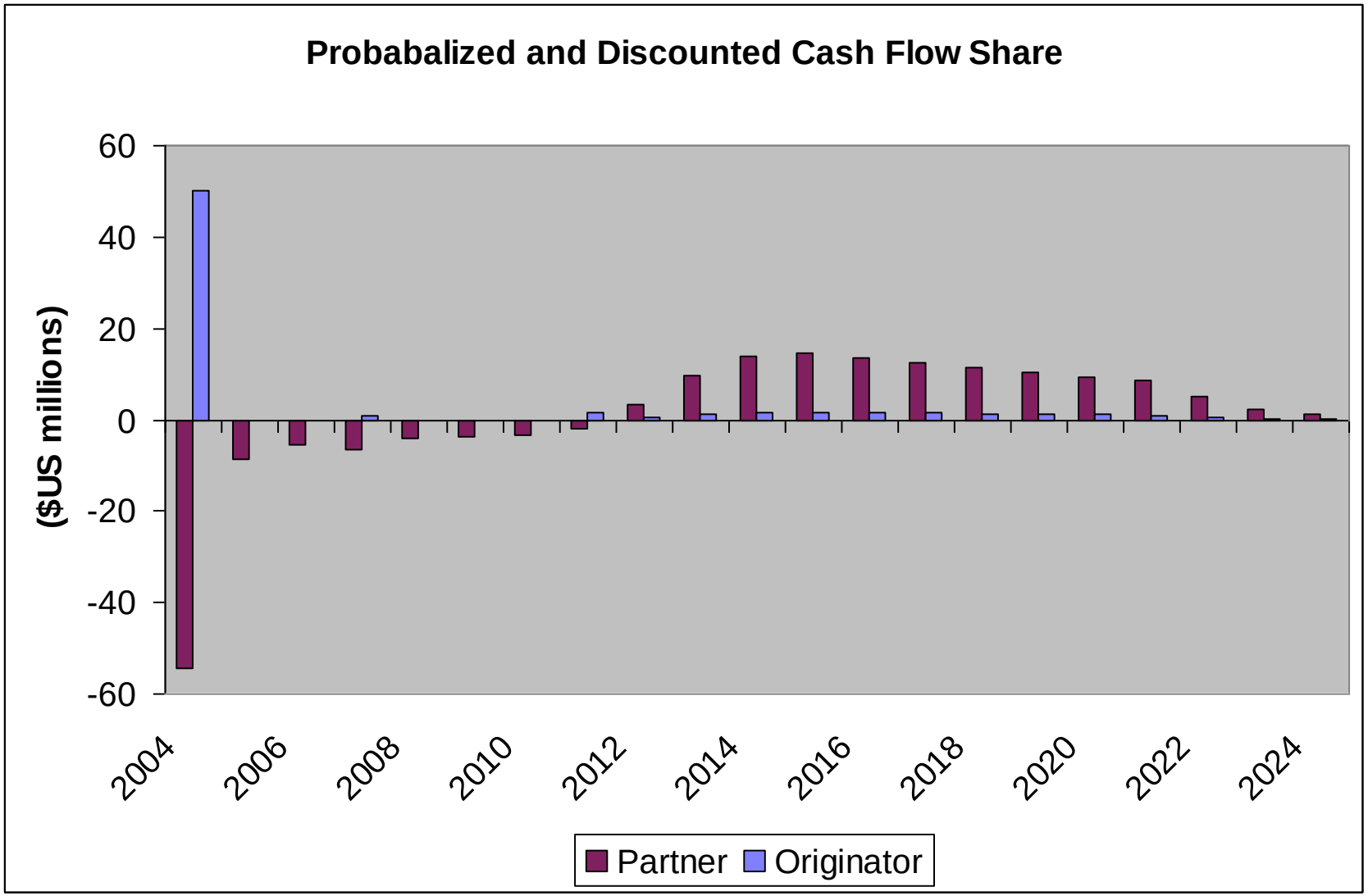
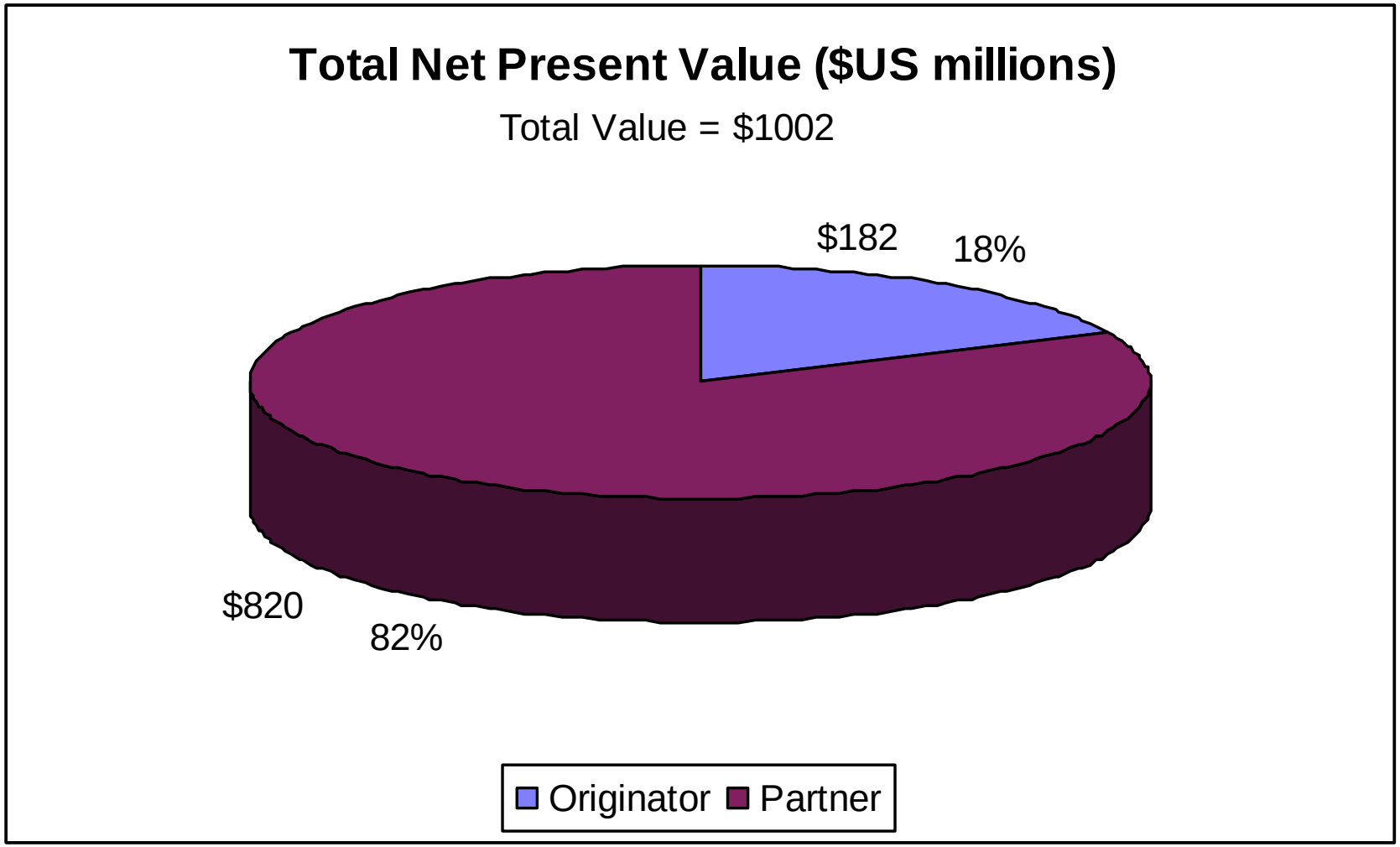
Risk and Value Sharing



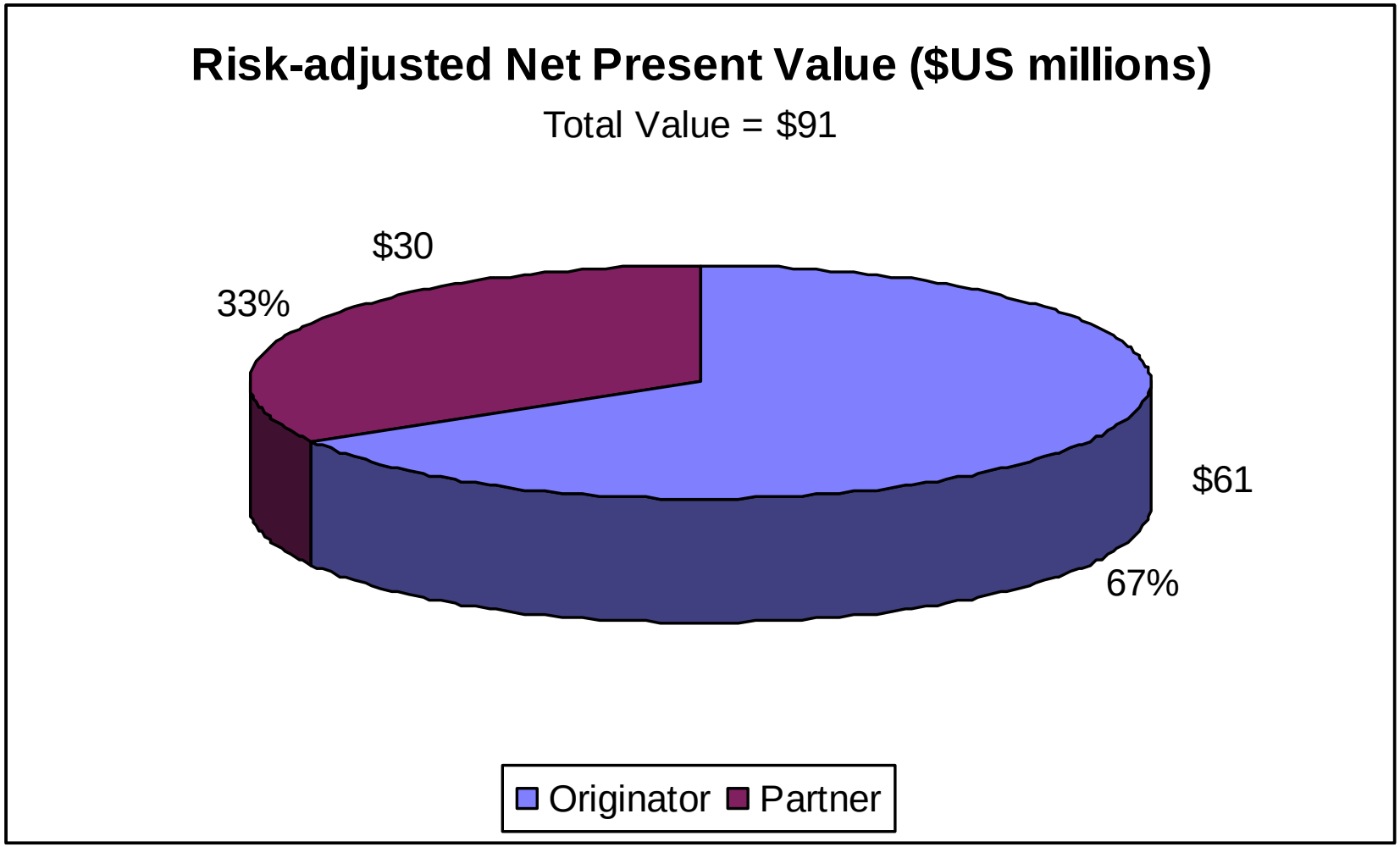
Adjusted Value Sharing



Shares of the Pie – Simple Method



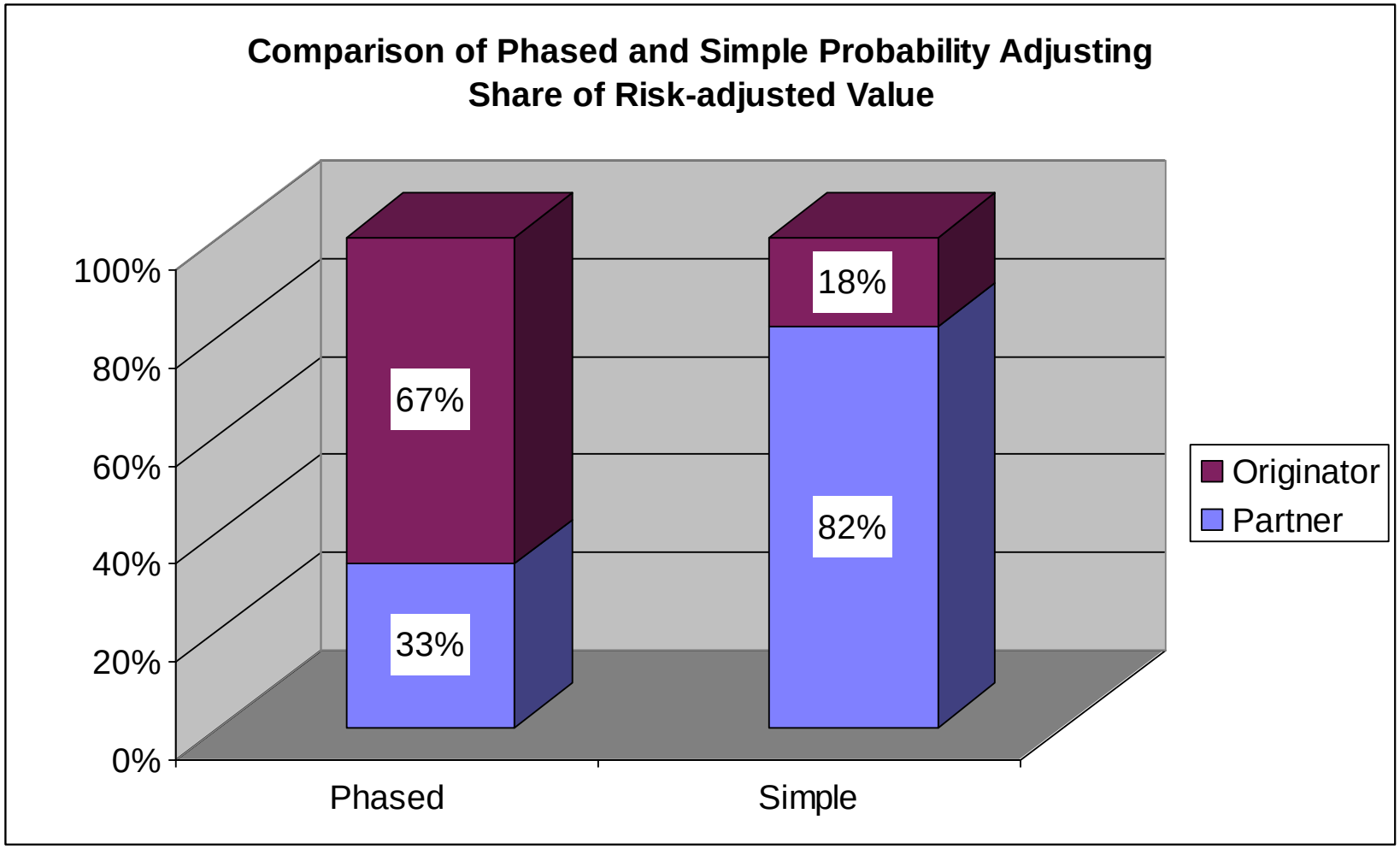
Resulting Shares of the Pie – Phased Method



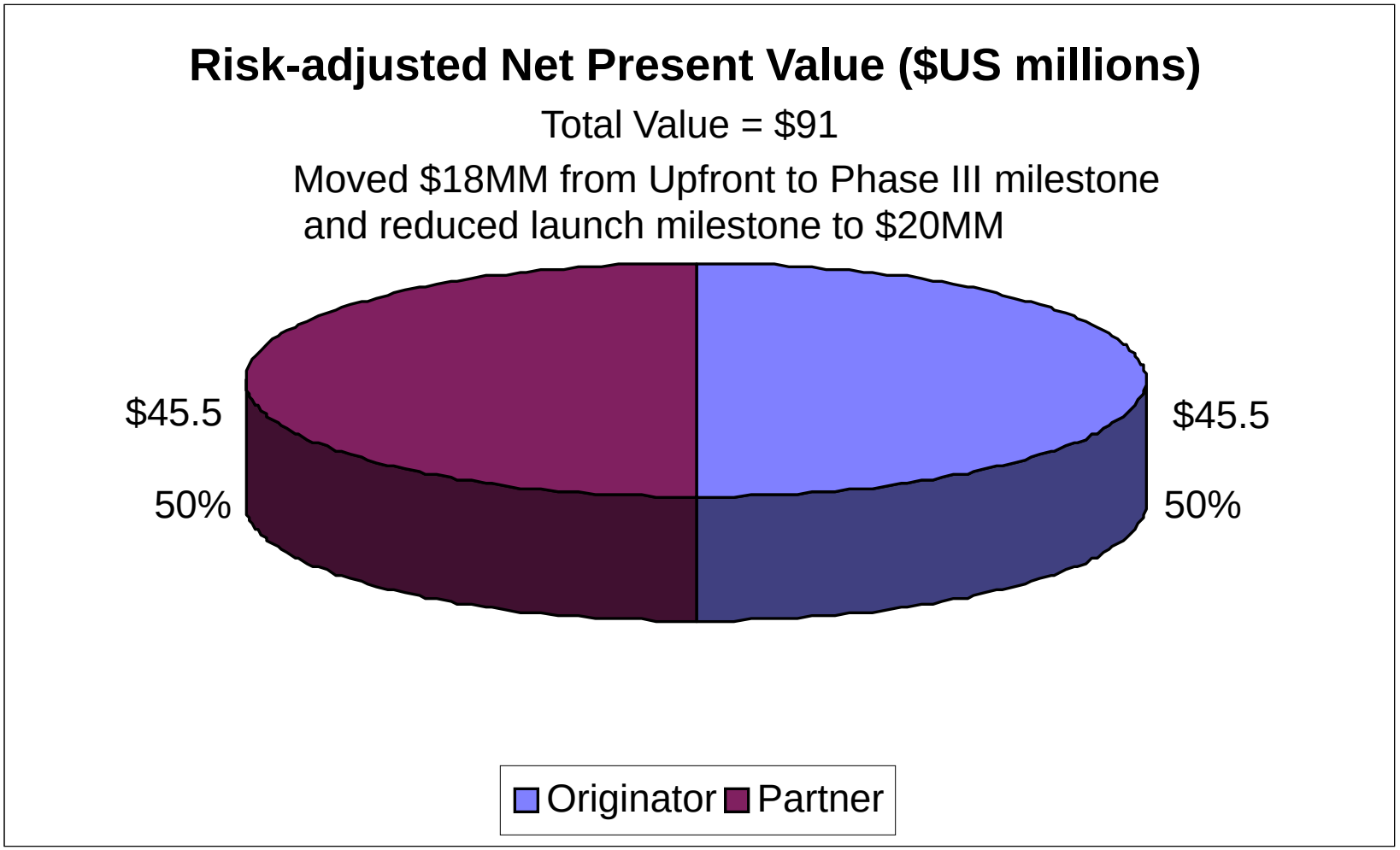
Interesting Note

Even with this skewed deal structure, it exceeds the partner's investment hurdle rate of 13.4% nominal.

Using the Phased Method is Worth the Effort



Impact of Changing Fees and Milestones



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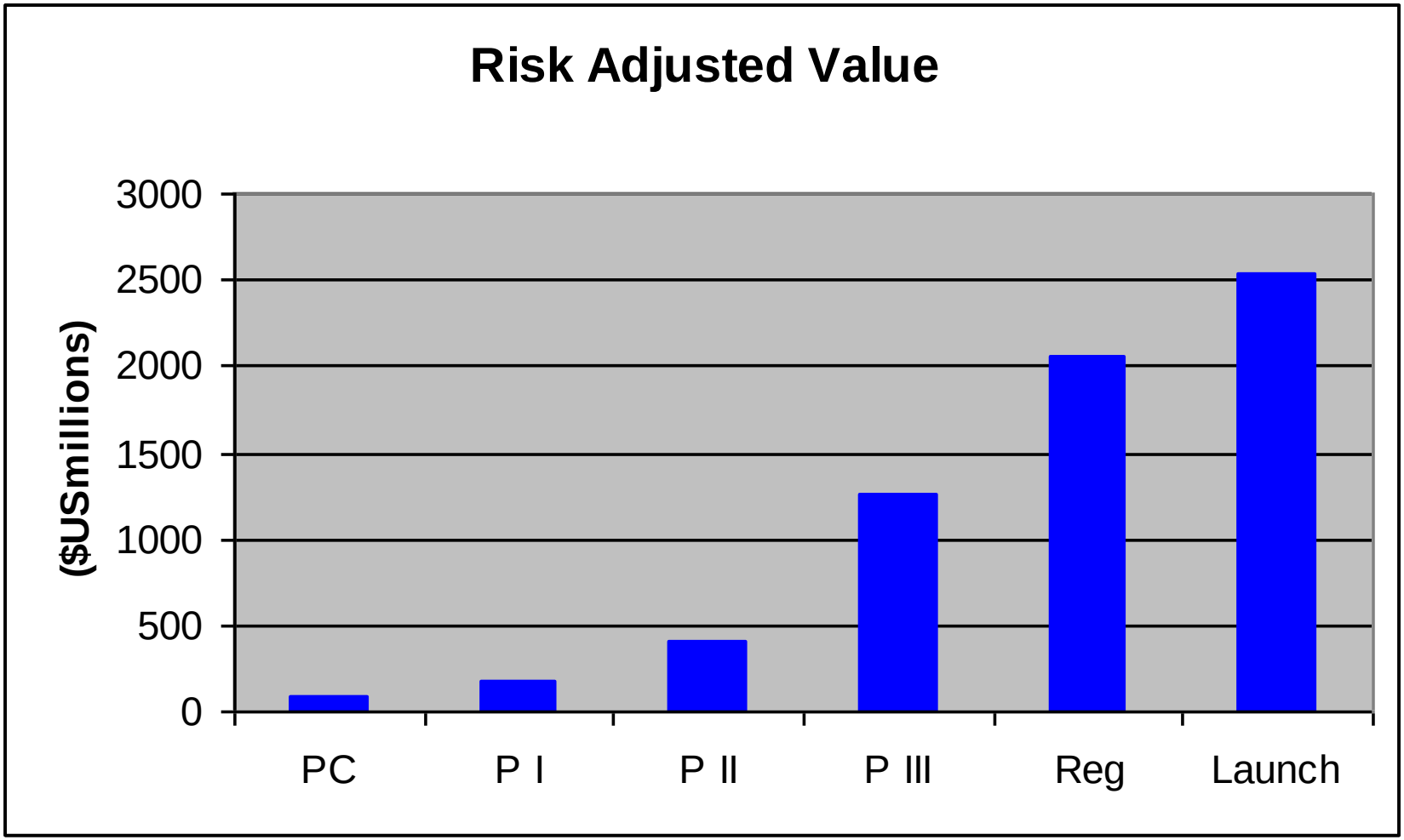
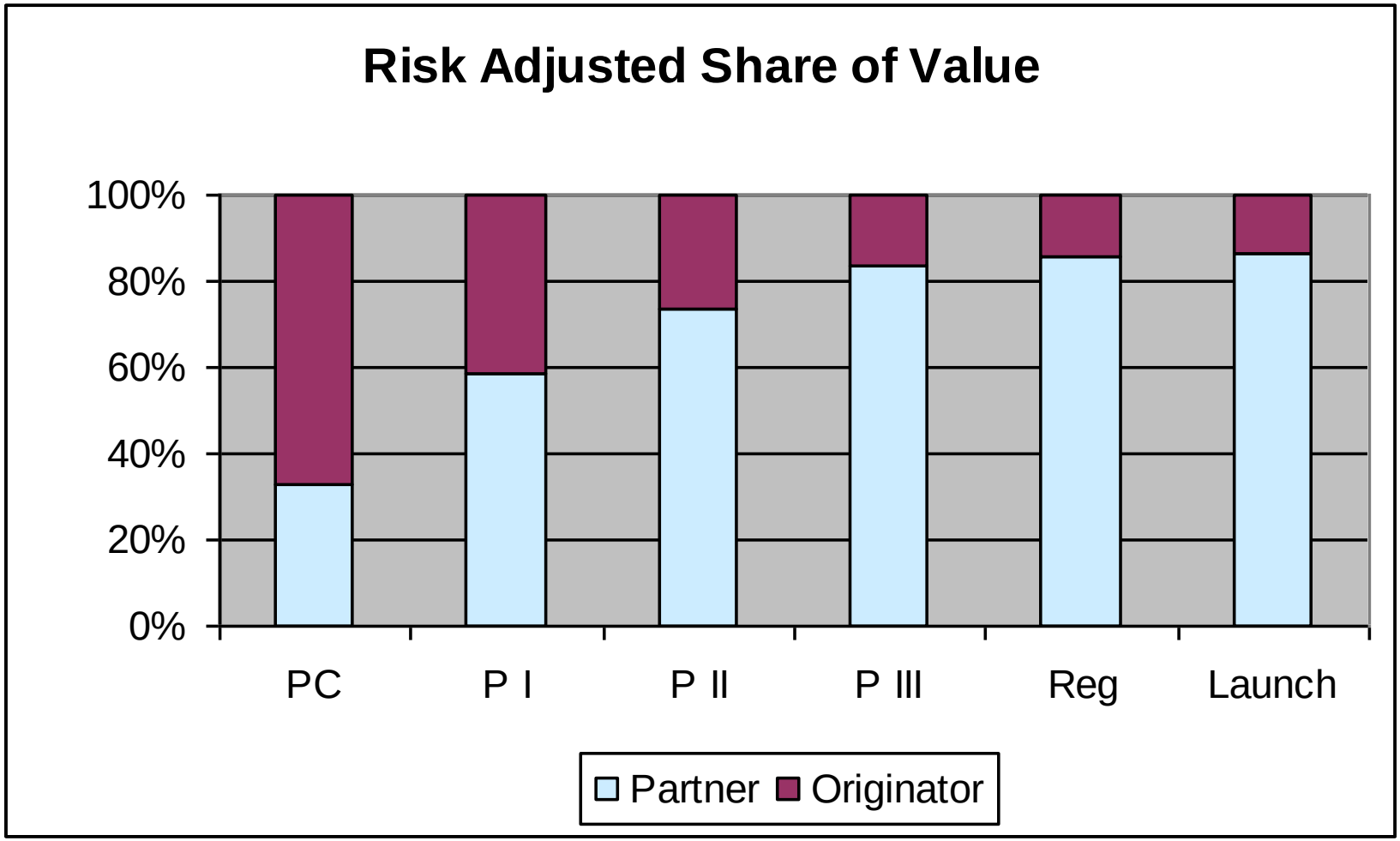
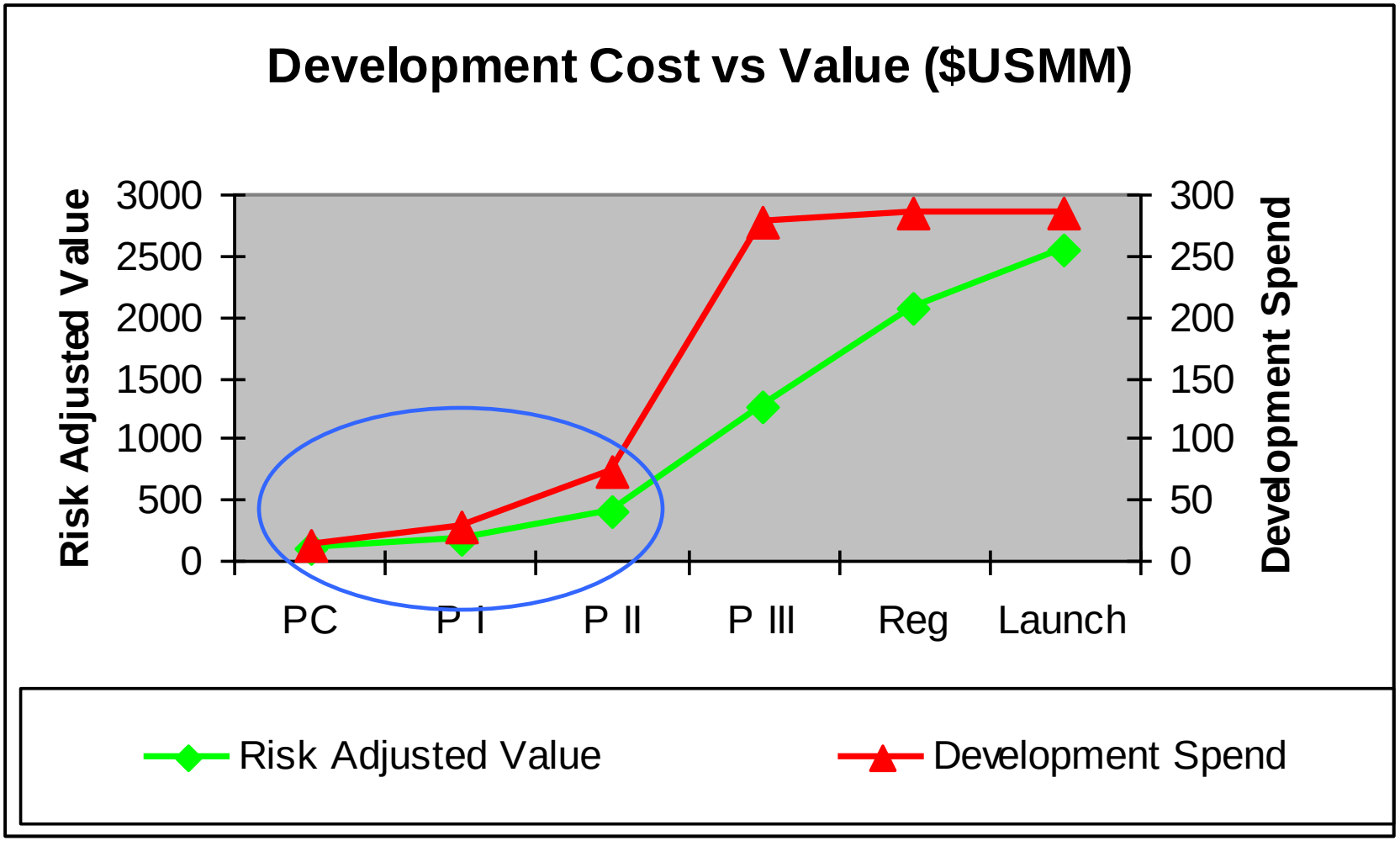
Value Adding



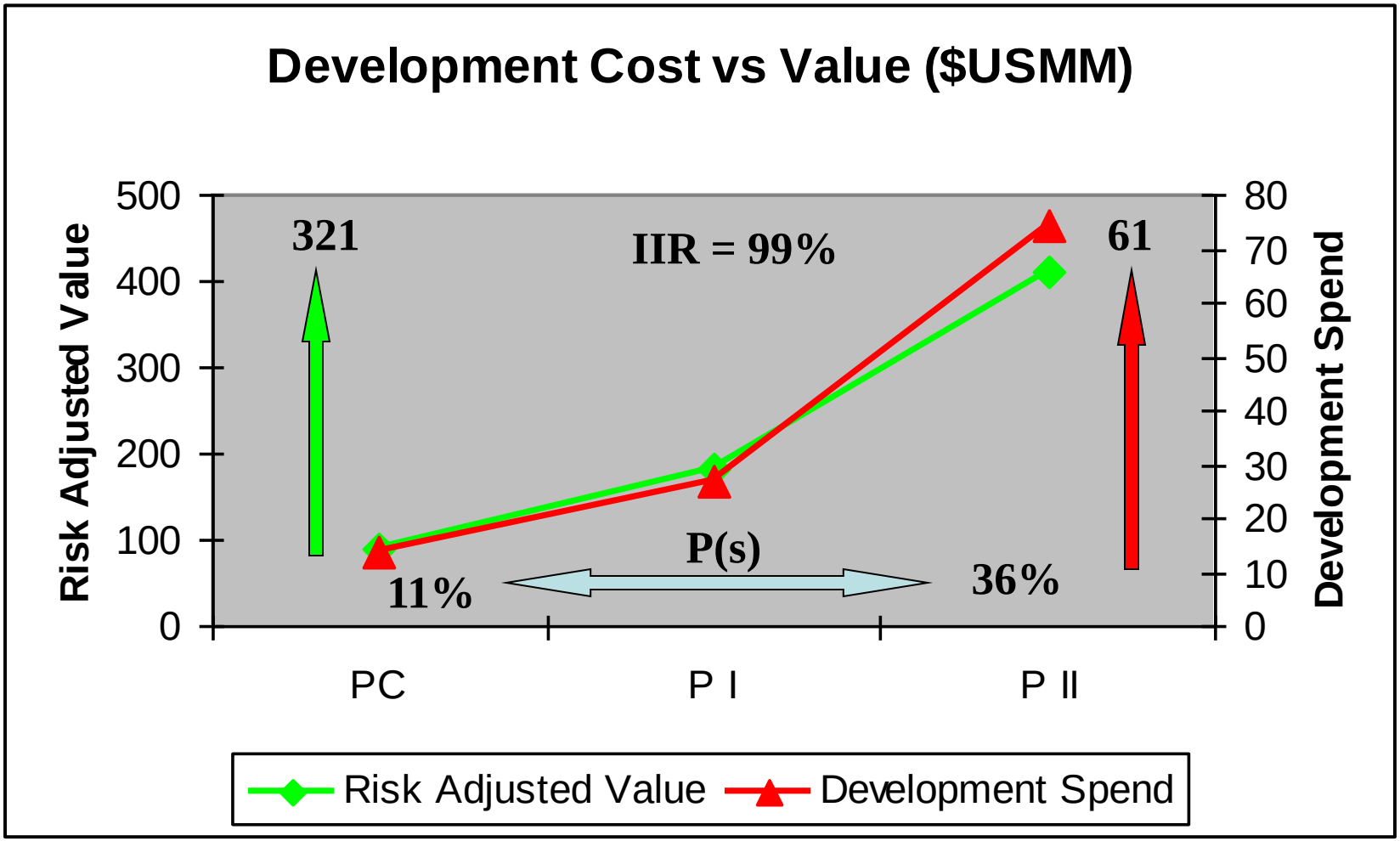
Partnering Timing - Shifting Value Shares



Pre-Partnering - Investment vs. Return



Pre-Partnering - Investment vs. Return



Model Strengths and Weaknesses

- Strengths of robust models
  - Transparency of key assumptions and variables
  - Flexibility in setting/changing parameters
  - Allows war-gaming and real-time negotiation back-up
  - Speaks decision maker's language
  - Provides charts and graphs for presentations
- Weaknesses of some models
  - Sensitive to discount rate and terminal value
  - Discount rates sometimes arbitrary
  - Scenario testing can be time-consuming
  - May not handle risk well
  - May not handle options and "what-ifs" well
  - Formula errors can lurk without being noticed

Remember - It's Not the Math

"Beware of geeks bearing formulas."

— Warren Buffet

Finer Points of Deal-making

- Adjusting Deal Structure to bridge disconnects

Cost of Capital	***Cost of future capital to be invested***
Probability of success	***Upfront, milestones & options***
Timing of achievements	***Milestones, options***
Revenue (units, price, lifecycle)	***Royalty rate & "bonus" payments***
Terminal Value	***Term, royalty tier, option***
Costs & Expenses	***Definitions, limits, sharing***
Performance	***Definitions, limits, bonus payments***
Cash needed is less than value	***M&A, equity stake, loans***
Out-licensor wants to develop	***R&D subsidies, staff sharing***
Out-licensor wants to market	***Profit share, S&M share, splits***

Thank You

Joe Dillon

President

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