



Advanced Business Development Course

Valuation and Deal Structuring

Valuation and Deal Structuring

Prepared for:

BIO's

Advanced Business Development Course

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President

DILLONCAPITAL
STRATEGIES



Bringing money to medicine[©]

A Word from the Attorneys

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Valuation and Deal Structuring Program

08:30 **Valuation and Deal Structuring Concepts and Trends**

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 *Program Concludes*

17:30 **Networking Reception**

A Word from Grizzled Deal Makers

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



– Pharma Exec

Before We Get Started

- ❑ **Your colleagues here** – Know them & learn from them
- ❑ **People's expertise differ** – Be patient and grow
- ❑ **The case study** – Listen for helpful hints during lecture
- ❑ **The model** – Essential, but its not just the math
- ❑ **Timing** – Keep moving, no analysis paralysis
- ❑ **Checkpoints** – Make goals and observe checkpoints
 - Today
 - Tomorrow
 - Last day
- ❑ **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 present. Strategy, Business Development, Forecasting and Analytics. Sit on Boards.
- ❑ **Small pharma** – 1996 to 2003. Positions as 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** – BBA in Finance, MBA in International Finance and several years teaching at the graduate level.

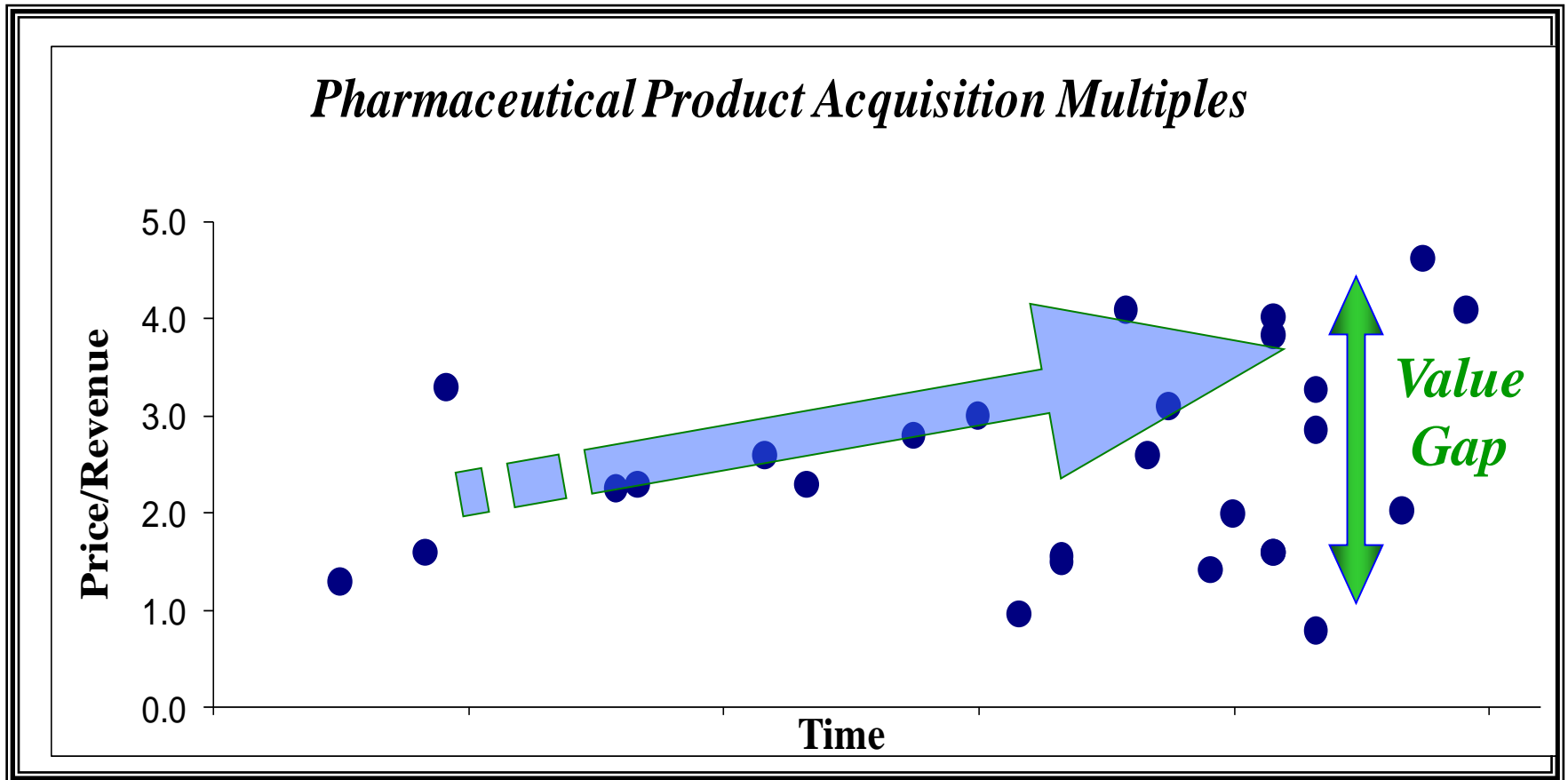
Focus: Partnering/BD, strategic planning, deal strategy, deal structuring, forecasting and valuations

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



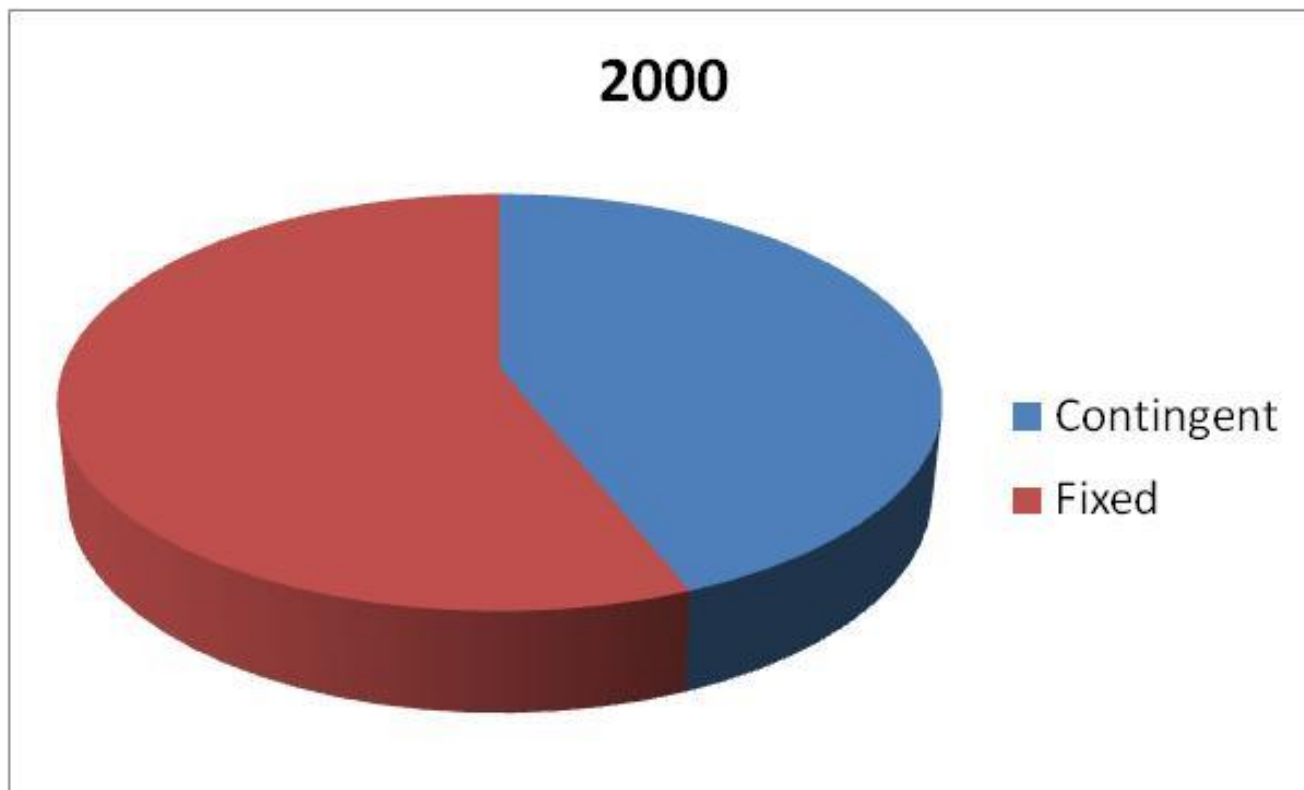
Multiples are a result, not a tool.

Deal Trends

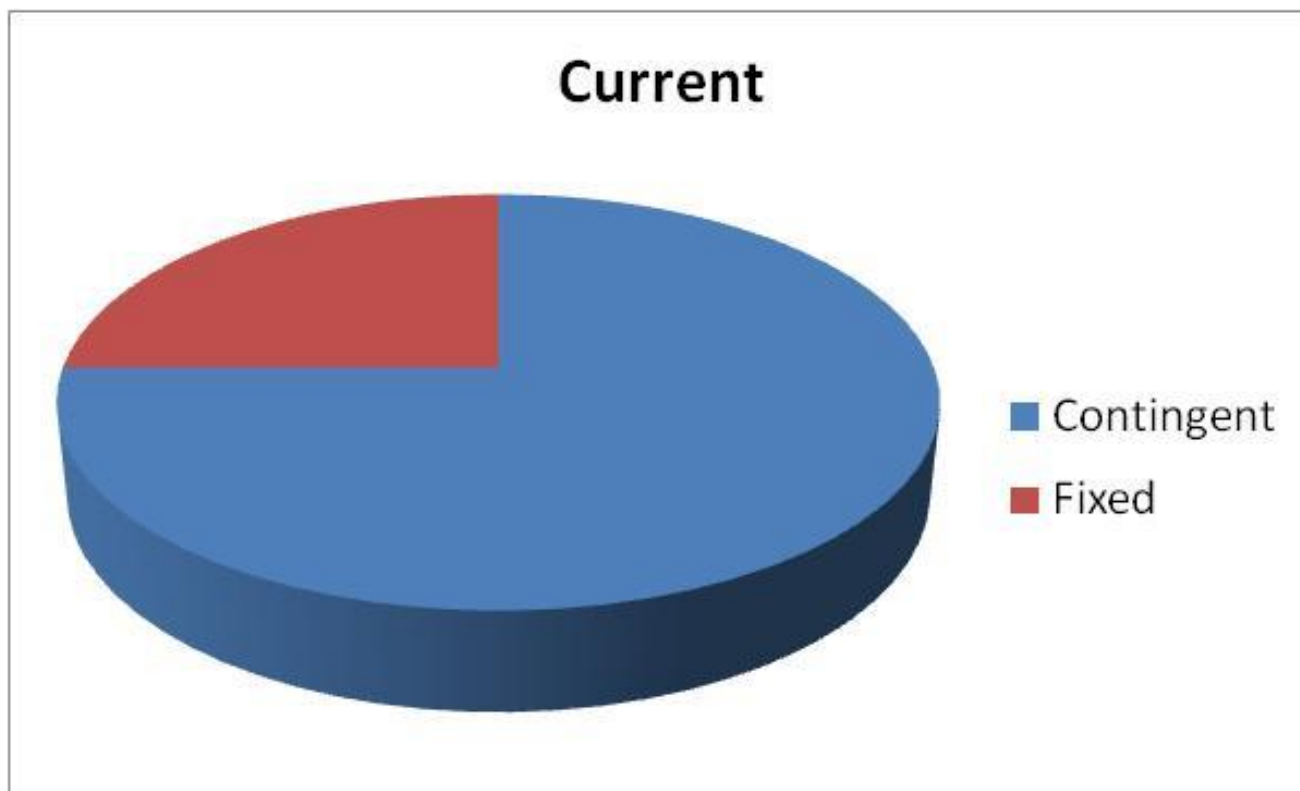
- ❑ **M&A Mania** – M&As by value up, 168% from 2013, even eclipsed the recent high in 2009. Allergan deal and commercial consolidation dominated. Biotech less than 10% of this volume.
- ❑ **Number of Biotech Out-licensing Deals** – Still running flat compared to recent years.
- ❑ **Value of those Deals** – Continued climb in valuations from already healthy levels. Early stage values up, as are upfronts.
- ❑ **Survival of the Bigs** – M&A, including “biobuck” acquisitions, continue. Embracing early stage market. Partnering with each other. Research platform collaborations still up.
- ❑ **Survival of the Smalls** – Novel, interesting technology high demand/value, “me-toos” still a tough sell. Option deals/earn-outs the new reality. Capital markets healthy. IPO hot streak.

Risk sharing is the structure du jour

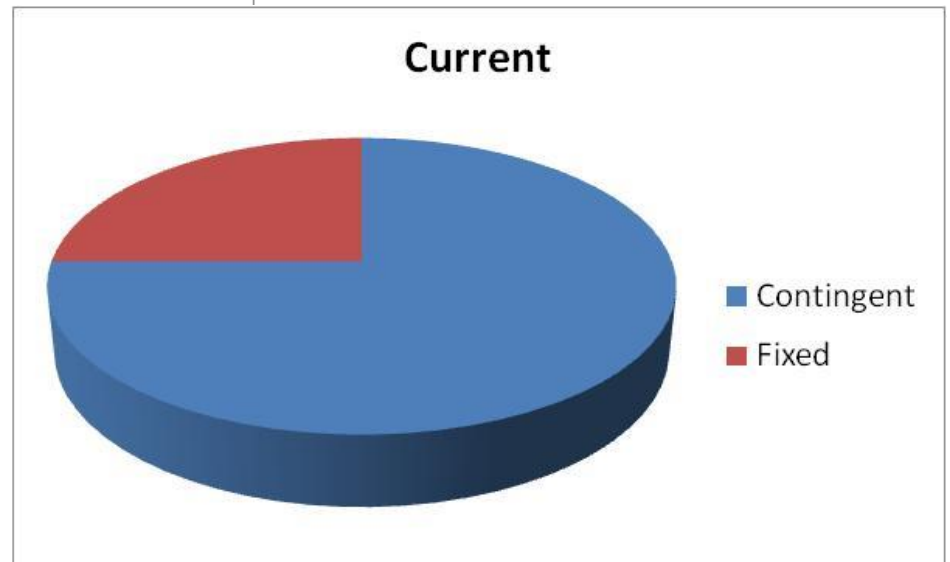
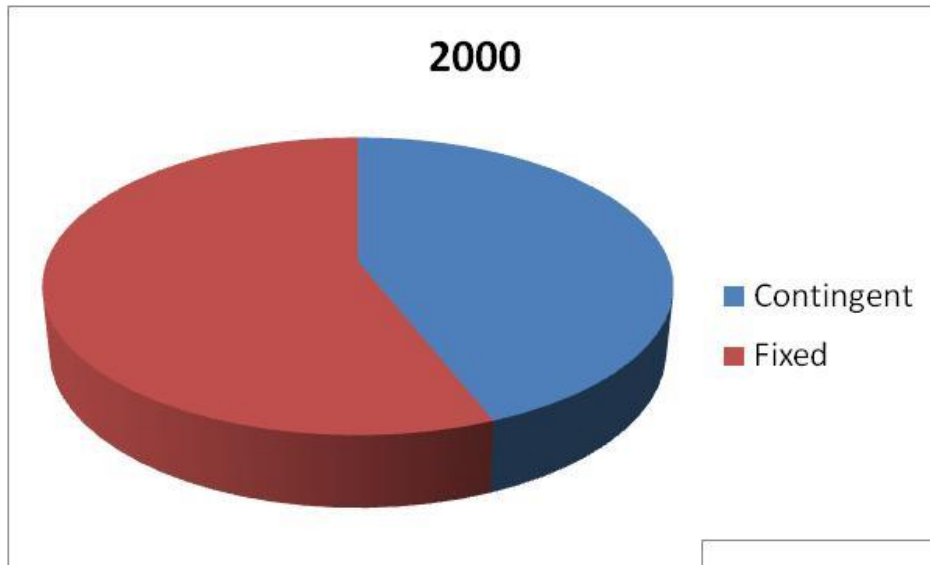
Game-changing Deal Structure Trend



Game-changing Deal Structure Trend



Game-changing Deal Structure Trend



What Drives Market Value?

- ❑ **Scarcity Value** – Simple supply and demand. More later.
- ❑ **Franchise Value** – The buy-side understands portfolio synergies, so they may bid above the stand-alone value of a product in order to enhance the value of the portfolio (or company) as a whole.
- ❑ **Time Value (of money)** – Over the past decade, internal WACC has decreased for most larger companies. Lower discount rates yield higher valuations. (more on this later)

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
- Pricing and reimbursement predictability

☐ **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!

Managing Risk and Sharing Value

- ❑ **Acquisitions that include “earn-outs” or contingent value rights (CVRs)**
- ❑ **Collaborative deals**
 - A twist on traditional “Option deals”
 - More gambles and rewards being shared
 - Risk/Value inflection points drive deal structure payments
 - Co-marketing/promotion deals far less common
- ❑ **Early stage deals**
 - Forecasting can be dicey at best, but a necessity
 - Values are being bid up, but pay-offs are contingent
 - Require more sophisticated modeling

Enter the new “norms”

The Sobering Fact

Most Deals Fail

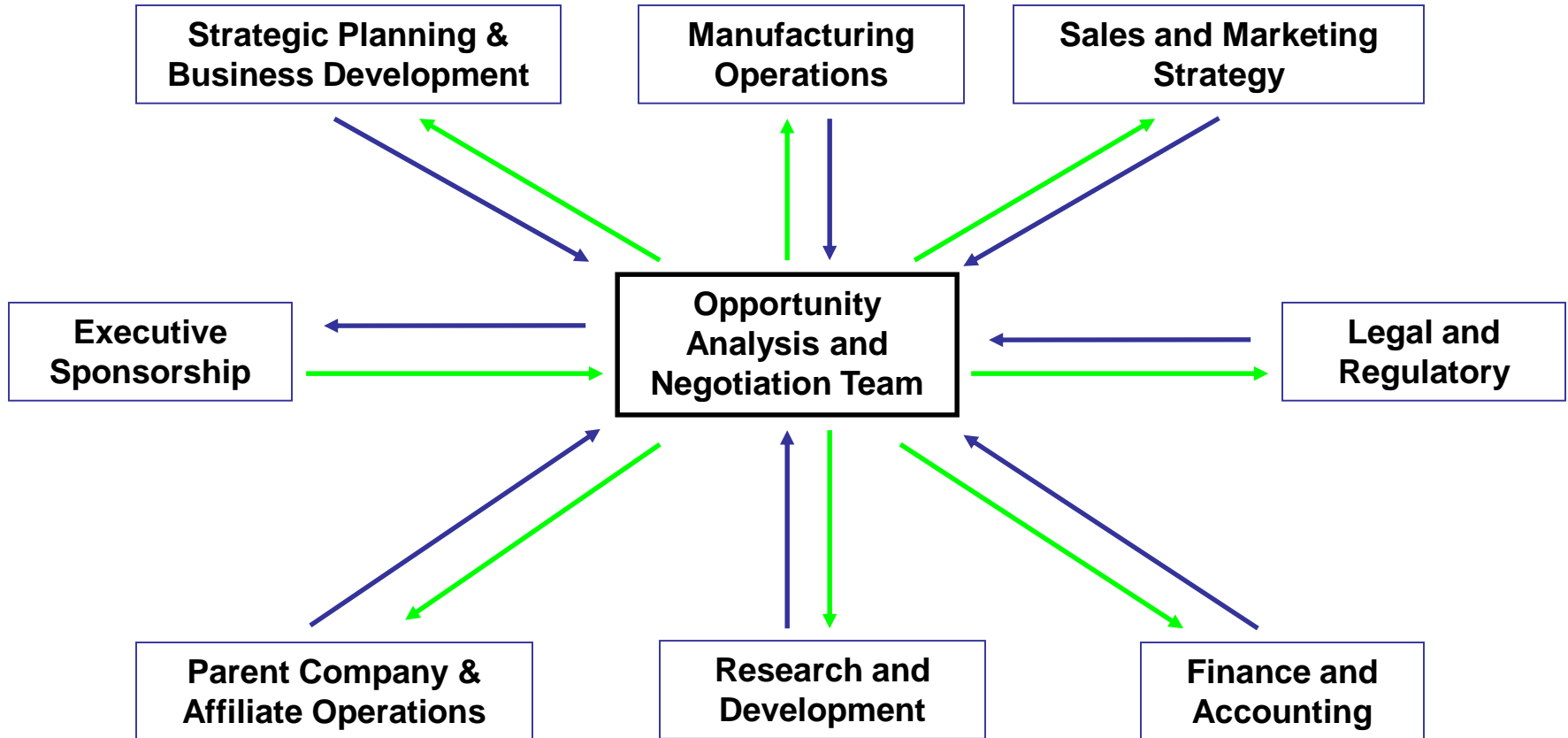
Depending on who you cite the number is 50 – 75%

Curious Fact

Products in an alliance have a far higher probability of success.

Clue: External diligence > Internal diligence

Deal Team Concept



Valuations are Not Done in a Vacuum!

The (e)Valuation Process

Valuations are opportunity evaluations and fact-finding processes yielding much more than “just a number”

- ❑ Define the **asset(s)** – what are its attributes, TPP?
 - Compare to the current/future market, needs and competition
- ❑ Measure the **investment** – what R&D is required?
- ❑ Assess the **risk** – what are the odds we succeed?
- ❑ Evaluate **partnering** – can we do this alone?
- ❑ Forecast **returns** – what’s the future cash flow?
- ❑ Consider **alternatives** – are other outcomes possible?
- ❑ Synchronize with **strategy** – how does this fit long-term?
- ❑ Structure the **deal** – what are feasible terms?

Fully understand the Value Proposition

Uses for Analysis and Valuations

- ❑ Provides defensible claim of value (100% of “buy-siders” say they use NPV on PC and later deals)
- ❑ Solid basis for discussions and negotiations
- ❑ Real-time deal terms and option strategy simulation
- ❑ Basis for comparison to alternative opportunities
- ❑ Support internal go / no-go decisions
- ❑ Develop operating plans / budgets
- ❑ Flush-out issues and “surprises”

The “devil” really is in the details.

Deal Valuation 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?

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
- Predictable pricing and reimbursement
- Risk mitigation
- IP protection
- Scarcity, franchise, and time values
- Lower costs

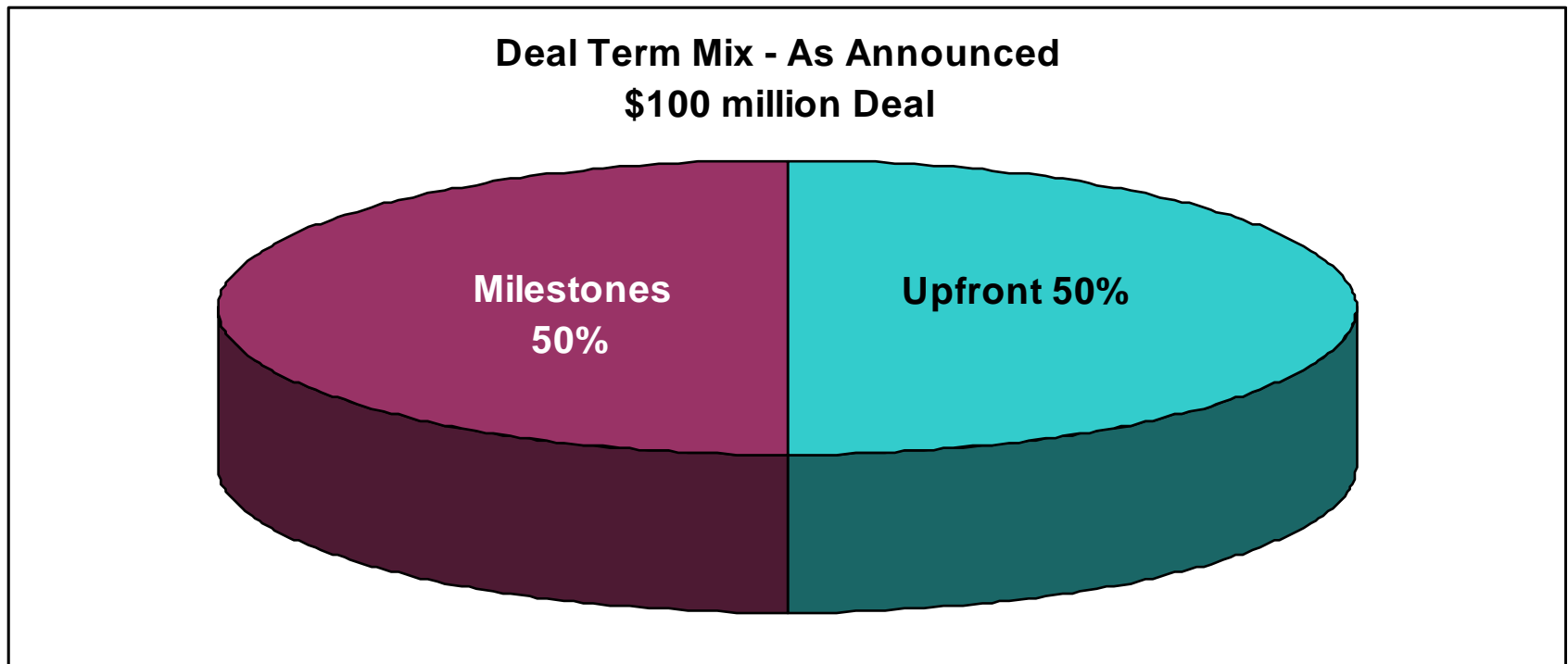
Value is in the wallet of the beholder.

Valuation Methodology

Which valuation methodology is best for technical programs?

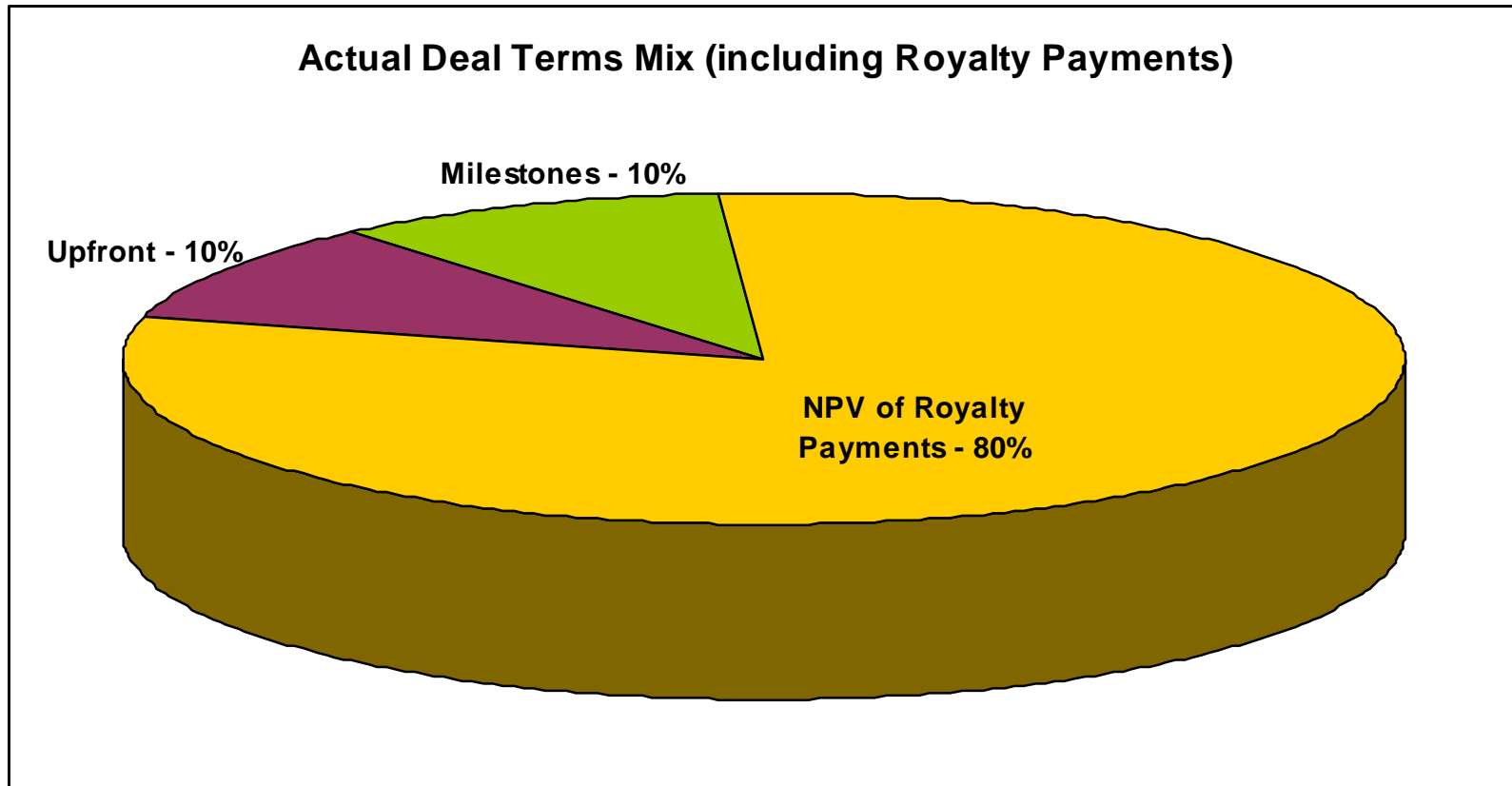
- Market – Comparables, standards or multiples?**
- Cost Basis?**
- Payback Period?**
- Income - Discounted Cash Flow (DCF) or NPV?**

Be Careful Using Comparables



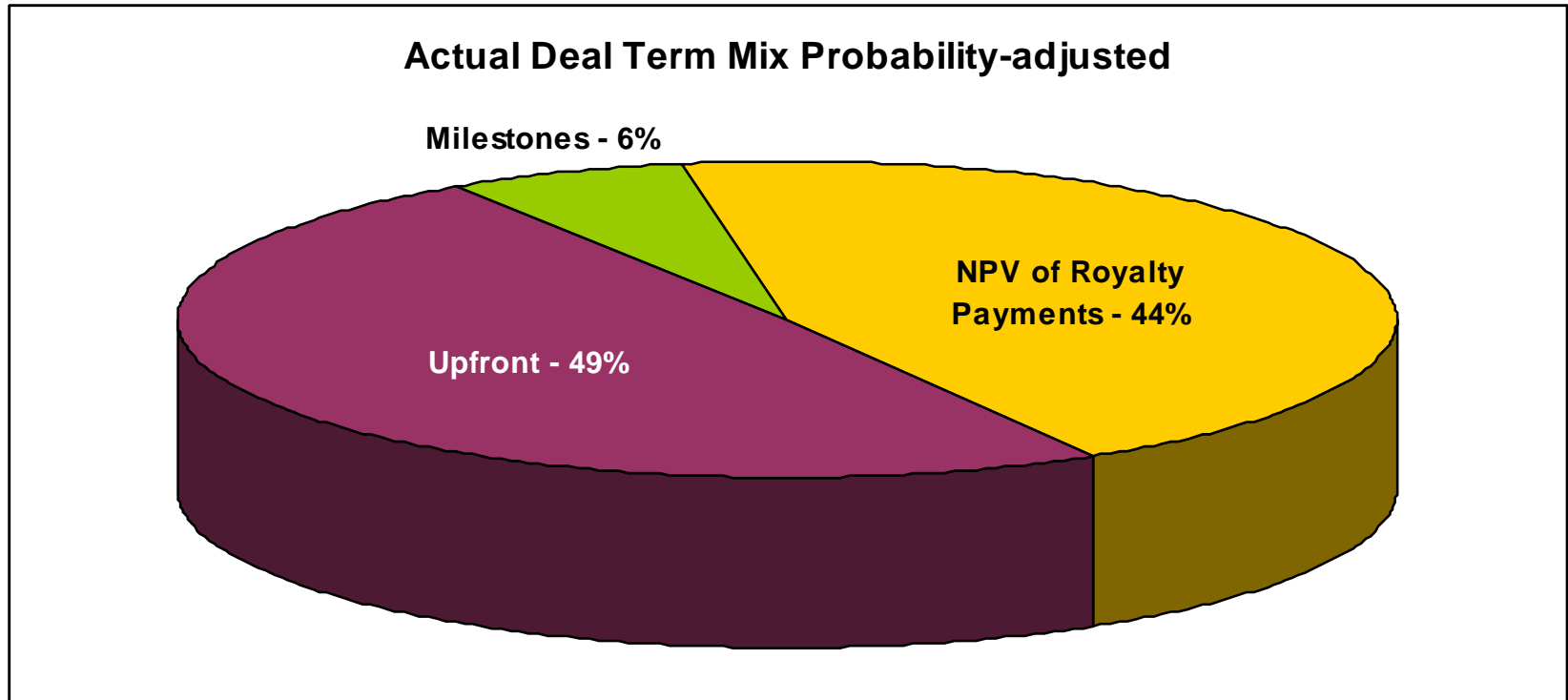
\$100 million? When? How? What-if?

Be Careful Using Comparables



A different perspective!

Be Careful Using Comparables



Getting Clearer?

Pharma/Biotech Valuation Methodology

□ Comparables?

- True, useful comps are rare. Critical info often not public.
- Best to have this info to make a “comp” useful
 - Target product(s) profile (TPP), how it would compete in the subject market, AND how it compares to your product
 - **Material** deal terms:
 - Field of Use and Geographic rights
 - Specifics of option timing and terms
 - Upfront payment and/or Option Fee(s)
 - Milestones – each payment, when paid and why
 - Royalty rate(s) and structure (e.g. tiers, net sales definition)
 - Expense/resource sharing or subsidies (esp. R&D and S&M)
 - Transfer price profits
 - Equity and/or debt purchases, rights and structures
 - Partnering scheme/strategies (e.g. co-promote options)
 - Options rights to other related or unrelated technologies
 - Etc., etc.....

Pharma/Biotech Valuation Methodology

- **Examples of non-public info in “comps”**
 - Buyer to purchase 19.9% of Seller’s common stock. **However, purchase price is at a 78% premium to stock’s public market value.**
 - Seller to pay \$5M upfront and “royalty” on approved product with ~\$300M revenue potential. **Buyer needs to re-launch product before allergy season - primarily interested in market momentum, transfer price profits and high royalties**
 - Buyer to pay >\$400M in milestones for PC product, **but >\$300M are for future (risky) indications in undisclosed therapeutic area(s)**
 - Seller takes deal with upfront <\$10M, milestones >\$300M and a “royalty.” **The bulk of the milestone payments were for practically unobtainable revenue levels and royalties were tiered at 20-33% where “net sales” definition made it similar to profit sharing.**
 - Buyer acquires PIII product with ~\$500M potential. Buyer does ~\$25M round to fund it. **Price unannounced. Seller rights unknown.**
 - Buyer acquires biotech, with PI lead, for \$500M. **Share purchase over years, contingent on future events and product valuations.**

Pharma/Biotech Valuation Methodology

- **“Standards” are only directional, at best**
 - Examples of standards include values of drugs by phase, value splits to partners, probabilities of success, market share, R&D and sales force costs, upfronts, milestones, royalty rates.
 - Survey data points often have very high deviation from average.
 - Life example: “What’s the price of that new car?” The average price of a car in Germany, in 2011, was €25,740. Is this “standard” helpful? Not really, there are many differences between models of cars.
 - In portfolio management, products in the same therapeutic area, same indications, and in the same phase of development must be valued independently to see which programs are emphasized or de-emphasized. Variations in valuations can be substantial.
 - In in-licensing, business development professionals at “buy-side” companies often have to discern between multiple opportunities within the same therapeutic area or indication, and often even within the same therapeutic target or specific technology.
 - Standards provide little, to no, application in these valuations.

On Terms and Value.....

**“Price is what you pay.
Value is what you get.”**



— Warren Buffet

BREAK!
(return at 10:00am)

Today's Program

08:30 Valuation and Deal Structuring Concepts and Trends

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 Program Concludes

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Pharma/Biotech Valuation Methodology



Comparables?

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



Multiples (Deal Value ÷ Most recent 12 mo. sales)?

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



Cost Basis?

- Prior R&D spending rarely an indicator of future value.



Payback?

- Ignores product lifecycle after payback.



Income - Discounted Cash Flow (DCF) or NPV

- Applicable to wide variety of technology opportunities
- Risk-adjusting a must for deal structuring
- Used by all “buy-siders” polled in a large survey

Focus on Risk and Return (“Cash is King”)

Use of NPV/rNPV and Deal Value

☐ **According to Recent “Deal Surveys”:**

- “Buy-siders” involved in PC or later deals say they use rNPV to value and structure deals.
- “Sell-siders” are less likely to use rNPV than “buy-siders.”
- Sell-siders who said they used rNPV had consistently and significantly higher upfronts, milestones, royalty rates and overall deal value than average.
- Sell-siders with far lower than average upfronts, milestones and royalty rates were least likely to use NPV prior to deal negotiations.

☐ **My Observations after >300 deal analyses:**

- Buy-siders do not normally disclose to the sell-side that they are using NPV or rNPV, nor share those NPV results with the sell-side.
- Sell-siders who do not do NPVs also tend to produce revenue forecasts that are “suspect” (to be kind).

The Investment in Analysis is Worth It!

Net Present Value (NPV)

Definition

Present value of a project's cash flows – including the invested capital (project cost) discounted at an appropriate discount rate.

Equation

$$\text{NPV}(i, N) = \sum_{t=0}^N \frac{R_t}{(1+i)^t}$$

Or use the formula function in Excel for NPV.

“R” represents each year's cash flow. “i” represents the discount rate. “t” represents the respective year of the cash flow.

Decision Rule

If NPV is zero or positive, consider doing the project; the more positive, the better. A NPV of zero indicates that the project has a rate of return exactly equal to the discount rate, so the discount rate is the same as the internal rate of return (IRR).

Risk-adjusted Net Present Value (rNPV)

Definition

- ❑ Same as NPV, except that future cash flows are probability-adjusted prior to discounting with the discount rate. More on risk later.

Pros


- ❑ For projects with significant uncertainties in cash flows, such as drugs, devices and diagnostics in various stages of development, results are much more accurate and meaningful than NPV only
- ❑ Simulates the application of a decision tree model that reflects the ability to stop the project in case of technological failure
- ❑ Facilitates risk-shared deal structuring

Cons

- ❑ Requires careful consideration of risk (probability of success) at multiple points in a project's lifecycle
- ❑ Requires using an appropriate discount rate

Key Discounted Cash Flow Variables

- Variables which usually impact value the most:
 - Gross Revenue (price and units)
 - Discount Rate
 - Probability of Success
 - R&D and Sales and Marketing Costs
 - Rebates, Allowances and Returns (RARs)
 - Operating Expenses
 - Capital Spending
 - Deal Terms
 - Cost of Goods (increasingly important)
 - Working Capital
 - Taxes



Let's think of
some uses
for NPV of
DCF
analyses...

Think Incrementally!!!

Discount Rates

□ What is a discount rate (in DCF valuations)?

- The discount rate is the rate of “interest” required to justify putting capital at risk and/or waiting for a future pay-back.
- It reflects revealed time preferences and opportunity costs

□ Why is it used?

- Think about it – if someone offers you the chance to invest \$10,000 to start a business today for a multiple pay-backs in the future, you need to consider that you’ll have the money tied up for some period of time without the ability to invest it in alternative options, and there is overall business risk that the pay-backs may not be as high as initially claimed.
- So, “discount” the forecast future cash flows by a rate that covers your “cost” and if the resulting net present value is above zero, you’ve earned your “discount rate” and more.

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

- For variable-risk projects (most all Biopharma transactions), probability of success (P(s)) is not included as a component of the discount rate. P(s) is treated separately. More later.
- Use care when mixing real and nominal figures
 - “Nominal” includes inflation, “Real” does not (lower rate)
- Rates differ widely by company
 - Possible higher valuations with established deal partners

Repeat – Leave project risk out of it!

Discount Rates (continued)

□ Which rate to use?

- Weighted average cost of capital (WACC)
- Average or typical WACC for firms in the industry
- Project-specific discount rates
- Real or nominal discount rates
- Hurdle rate or IRR required by top management or investors

Discount Rates (continued)

Cost of Equity Capital

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

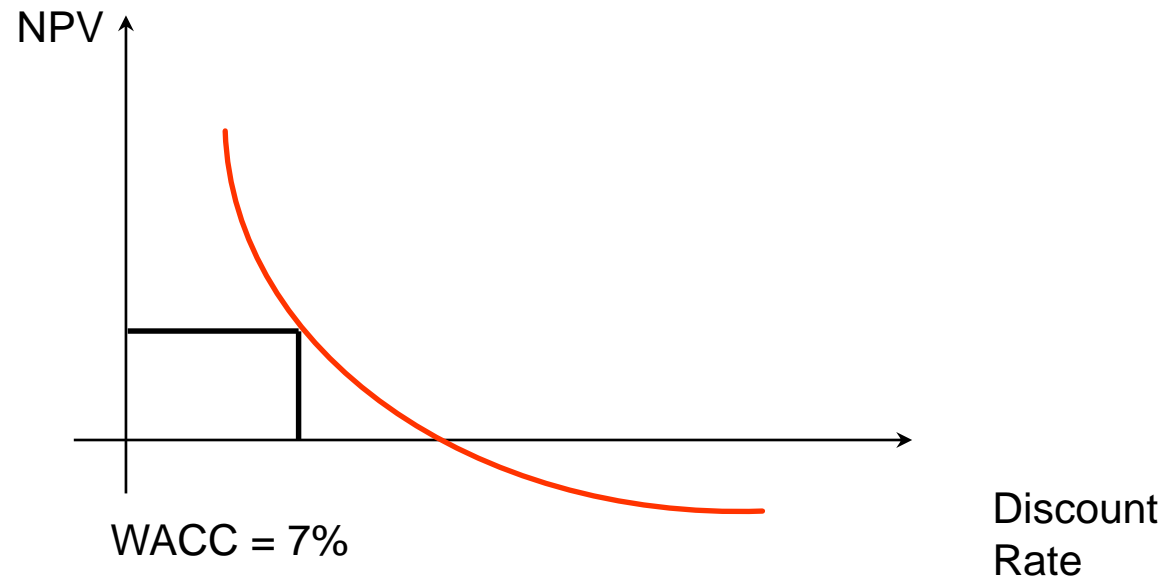
Return for a specific Investment	E	
Risk-free rate	I	3.32% 10 year Treasury
Return for the equity market as a whole	M	10.72%
Market risk premium	(M - I)	7.40%
Small company/Liquidity premium	S	0.00%
Industry Premium	IP	4.00%
Total Cost of Equity Capital		14.72%
Rounded Cost of Equity Capital		14.7%

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%	

NPV vs. Discount Rate



Feasibility: Project must have $NPV > 0$

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

Discount Rate - Timing Matters

Year:		0	1	2	3	4	5	6	10	14
Discount Rate	15%									
Cash Flow	380.0	50.0	-	50.0	-	-	50.0	20.0	70.0	20.0
Present Value of Cash Flow		50.0	-	37.8	-	-	24.9	8.6	17.3	2.8
Net Present Value	\$172.5									

Year:		0	1	2	3	4	5	6	10	14
Discount Rate	15%									
Cash Flow	380.0	150.0	-	-	-	-	50.0	20.0	20.0	20.0
Present Value of Cash Flow		150.0	-	-	-	-	24.9	8.6	4.9	2.8
Net Present Value	\$222.3									

Year:		0	1	2	3	4	5	6	10	14
Discount Rate	15%									
Cash Flow	380.0	-	-	-	-	-	150.0	20.0	20.0	70.0
Present Value of Cash Flow		-	-	-	-	-	74.6	8.6	4.9	9.9
Net Present Value	\$129.1									

Hidden years each have \$20.0 cash flow.

Discount Rate Matters

Year:		0	1	2	3	4	5	6	10	14
Discount Rate	15%									
Cash Flow	380.0	50.0	-	50.0	-	-	50.0	20.0	70.0	20.0
Present Value of Cash Flow		50.0	-	37.8	-	-	24.9	8.6	17.3	2.8
Net Present Value	\$172.5									
Year:		0	1	2	3	4	5	6	10	14
Discount Rate	8%									
Cash Flow	380.0	50.0	-	50.0	-	-	50.0	20.0	70.0	20.0
Present Value of Cash Flow		50.0	-	42.9	-	-	34.0	12.6	32.4	6.8
Net Present Value	\$235.1									
Year:		0	1	2	3	4	5	6	10	14
Discount Rate	22%									
Cash Flow	380.0	50.0	-	50.0	-	-	50.0	20.0	70.0	20.0
Present Value of Cash Flow		50.0	-	33.6	-	-	18.5	6.1	9.6	1.2
Net Present Value	\$137.0									

Hidden years each have \$20.0 cash flow.

Risk Assessment

- ❑ Opportunity to double your money!
 - Pay \$1 for the opportunity to win \$2 if you correctly guess the result of a coin flip (heads or tails)
- ❑ Is this a good bet?



- ❑ Analysis
 - Odds of winning: 50%
 - Possible cash flows: -\$1 or +\$1
- ❑ The math – probability adjusting
 - $(-\$1 * 1.0) + ((\$2 * 0.5) + (0 * 0.5)) = \0
- ❑ The decision
 - Overtime this bet yields zero gain

Risk Assessment

- ❑ Probability of Technical Success – P(s)
 - Development (will the science work as planned?)
 - Regulatory (will it be approved for marketing?)
- ❑ Considerations
 - Break down by year, phase, study or major inflection points
 - P(s) is usually different year-by-year. And each year's cash flow must be individually risk adjusted to do deal structuring
 - Apply to the target product profile (TPP)
 - This is the profile of what is expected to launch
 - The rest of the forecasts (e.g. revenue) should also be for the TPP
 - Use P(s) comps or a qualitative and quantitative rating system
 - Consider the resources and capabilities that will be available

Risk changes over time

Risk Assessment

□ Overall P(s) is calculated as a progression

- The first year is often indicated as 100% probability because it is unlikely a program will be terminated before most or all of that year's budget is consumed. Remember, this exercise is to determine the probability of each year's cash flow.
- First, determine the probability of succeeding in each year, assuming success in the previous year (First line below)
- Then, by multiply each year's probability times the progressive probability of the previous year (Second line below)
- Years after marketing approval are indicated as 100% (assumed success)

Year:		0	1	2	3	4	5	6	10	14
Probability of Success P(s)	30%	100%	70%	70%	80%	80%	95%	100%	100%	100%
Progressive P(s)		100%	70%	49%	39%	31%	30%	30%	30%	30%

Probability of Success - Timing Matters

Year:		0	1	2	3	4	5	6	10	14
Probability of Success P(s)	30%	100%	70%	70%	80%	80%	95%	100%	100%	100%
Progressive P(s)		100%	70%	49%	39%	31%	30%	30%	30%	30%
Cash Flow	380.0	50.0	-	50.0	-	-	50.0	20.0	70.0	20.0
Risk-adjusted Cash Flow		50.0	-	24.5	-	-	14.9	6.0	20.9	6.0
PV of Risk-adjusted Cash Flow		50.0	-	18.5	-	-	7.4	2.6	5.2	0.8
Net Present Value @ 15%	\$93.7									

Year:		0	1	2	3	4	5	6	10	14
Probability of Success P(s)	30%	100%	70%	70%	80%	80%	95%	100%	100%	100%
Progressive P(s)		100%	70%	49%	39%	31%	30%	30%	30%	30%
Cash Flow	380.0	150.0	-	-	-	-	50.0	20.0	20.0	20.0
Risk-adjusted Cash Flow		150.0	-	-	-	-	14.9	6.0	6.0	6.0
PV of Risk-adjusted Cash Flow		150.0	-	-	-	-	7.4	2.6	1.5	0.8
Net Present Value @ 15%	\$171.5									

Year:		0	1	2	3	4	5	6	10	14
Probability of Success P(s)	30%	100%	70%	70%	80%	80%	95%	100%	100%	100%
Progressive P(s)		100%	70%	49%	39%	31%	30%	30%	30%	30%
Cash Flow	380.0	-	-	-	-	-	150.0	20.0	20.0	70.0
Risk-adjusted Cash Flow		-	-	-	-	-	44.7	6.0	6.0	20.9
PV of Risk-adjusted Cash Flow		-	-	-	-	-	22.2	2.6	1.5	2.9
Net Present Value @ 15%	\$38.5									

Hidden years each have \$20.0 cash flow.

Probability of Success % Matters

Year:		0	1	2	3	4	5	6	10	14
Probability of Success P(s)	30%	100%	70%	70%	80%	80%	95%	100%	100%	100%
Progressive P(s)		100%	70%	49%	39%	31%	30%	30%	30%	30%
Cash Flow	380.0	50.0	-	50.0	-	-	50.0	20.0	70.0	20.0
Risk-adjusted Cash Flow		50.0	-	24.5	-	-	14.9	6.0	20.9	6.0
PV of Risk-adjusted Cash Flow		50.0	-	18.5	-	-	7.4	2.6	5.2	0.8
Net Present Value @ 15%	\$93.7									
Year:		0	1	2	3	4	5	6	10	14
Probability of Success P(s)	45%	100%	80%	80%	87%	85%	95%	100%	100%	100%
Progressive P(s)		100%	80%	64%	56%	47%	45%	45%	45%	45%
Cash Flow	380.0	50.0	-	50.0	-	-	50.0	20.0	70.0	20.0
Risk-adjusted Cash Flow		50.0	-	32.0	-	-	22.5	9.0	31.5	9.0
PV of Risk-adjusted Cash Flow		50.0	-	24.2	-	-	11.2	3.9	7.8	1.3
Net Present Value @ 15%	\$112.3									
Year:		0	1	2	3	4	5	6	10	14
Probability of Success P(s)	15%	100%	55%	55%	70%	75%	95%	100%	100%	100%
Progressive P(s)		100%	55%	30%	21%	16%	15%	15%	15%	15%
Cash Flow	380.0	50.0	-	50.0	-	-	50.0	20.0	70.0	20.0
Risk-adjusted Cash Flow		50.0	-	15.1	-	-	7.5	3.0	10.6	3.0
PV of Risk-adjusted Cash Flow		50.0	-	11.4	-	-	3.8	1.3	2.6	0.4
Net Present Value @ 15%	\$74.2									

Hidden years each have \$20.0 cash flow.

Other Important Valuation Considerations

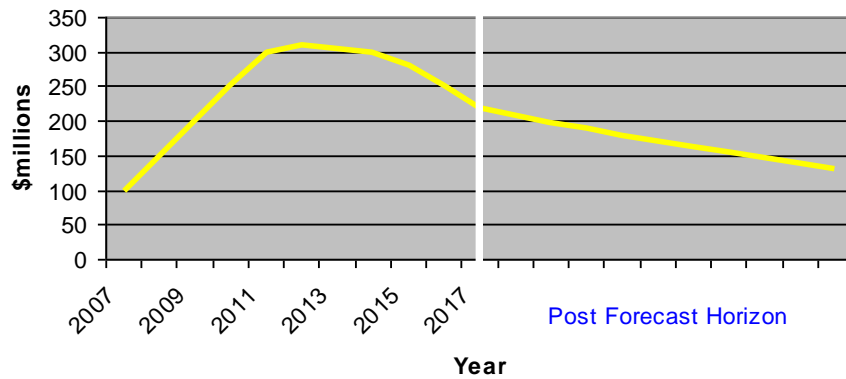
□ Terminal Value

- 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)
- It is best to forecast a cash flow out far enough to go at least a year beyond patent or exclusivity loss, which ever is later, so the terminal value factor applies to a “smoother” landing. Input -100% to simulate the termination of license rights.
- The terminal value factor is almost always negative. This is because it is very rare for a high tech product to maintain or grow value forever. There are exceptions.
- Terminal value can be a substantial value component, so be careful using and interpreting it.

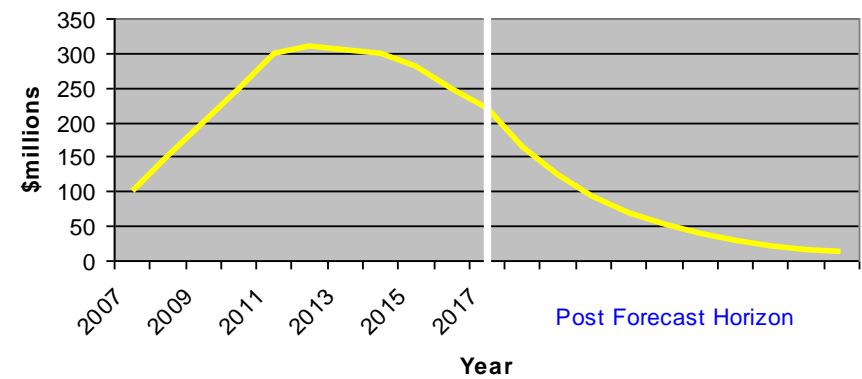
Other Important Valuation Considerations

Terminal Value Examples

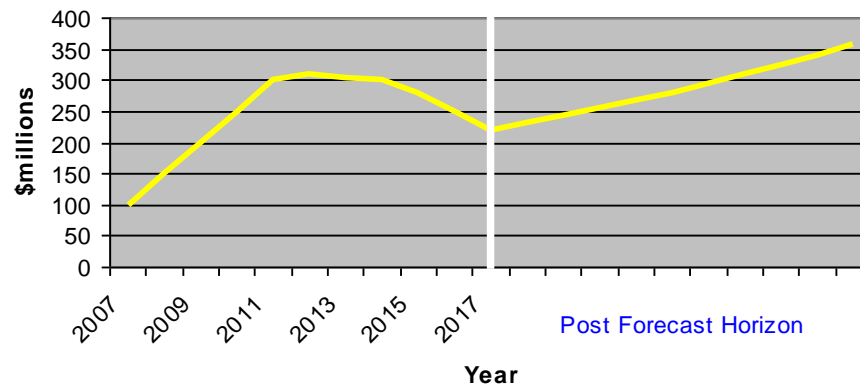
Terminal Value Growth Rate -5%



Terminal Value Growth Rate -25%



Terminal Value Growth Rate +5%



Working Capital

□ Working Capital

- Working capital is defined as (current assets – current liabilities).
- Our model uses the “incremental revenue factor” method, which is accurate and easier to apply than the accounting method.
- It’s considered an “investment” to support daily operations and provide adequate corporate solvency.
- As operations grow, more working capital investment is required.
- A typical pharma company adds working capital at a rate of 10% - 15% of incremental revenue.
- The need to increase working capital is considered a cost associated with projects that grow the company.
- Our model’s working capital input is expressed as a percentage of incremental revenue and adds it as a separate line after tax.

How to Deal with Inflation – Or Not

□ 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.
- To input 3% inflation, type the factor “1.03” in the field provided.
- I’ll describe this more during the case study.....

On Misreading the Human Factor.....

“I can calculate the movement of the stars, but not the madness of men.”



— Sir Isaac Newton
After losing a vast sum of money on
an investment in the South Sea Company

Beginning of Case Study Work

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

War-gaming Tools

Seat of the pants.....



Sopwith Camel

War-gaming Weapons

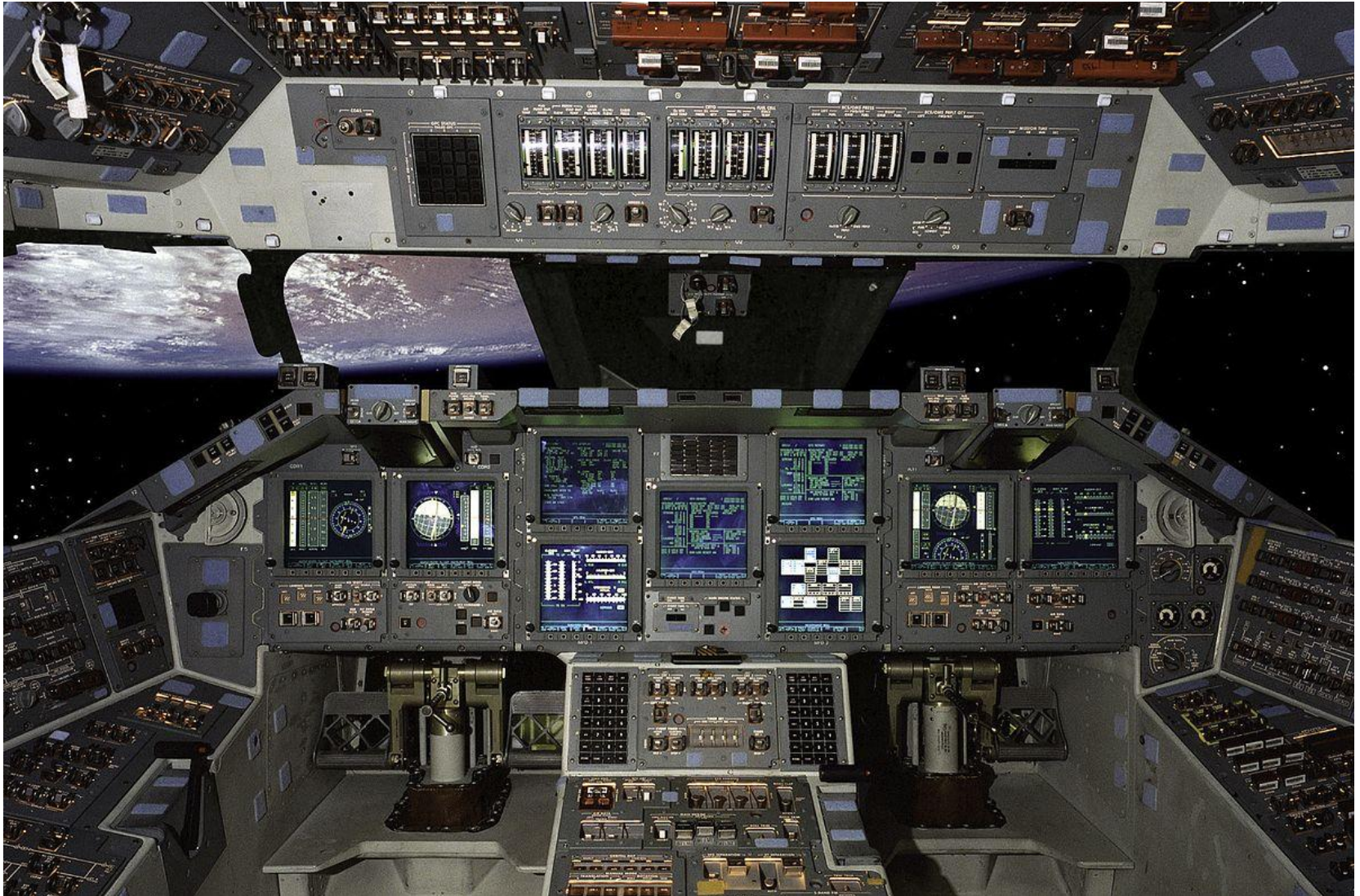
.....or “heads up display”



F-14 Tomcat

War-gaming Weapons

.....or world domination



Step into the Cockpit

DCS Opportunity Valuation and Gaming Model

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Bringing money to medicine®

Sheet: Cockpit

Product: **Product X**

In-Licensor: **In-licensor**

Out-Licensor: **Out-licensor**

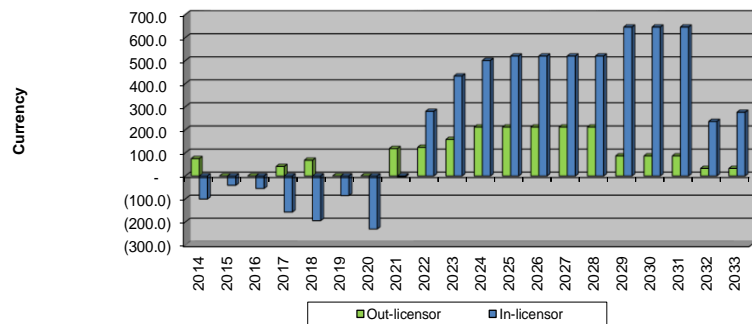
License Expiration: 31-Jan-19

1,727 days remaining on license period.

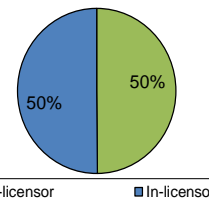
	2014	Total Product Value		Value to Out-licensor		Value to In-licensor	
		Value Components	Consolidated	Value Components	Consolidated	Value Components	Consolidated
First Year of Cash Flow	2014						
Real Discount Rate	8.74%						
Nominal Discount Rate	12.00%						
Inflation Factor	1.03						
Marginal Tax Rate	32.0%						
Working Capital as % Revenue	10.0%						
Terminal Value Growth Rate	-15.0%						
Scenario Multiples							
Sales	1.0						
Cost of Goods Sold	1.0						
Sales & Marketing	1.0						
Research & Development	1.0						
Other Operating Expenses	1.0						
Name of 4th Territory	ROW						
Figures in:	USD (millions)						
		NPV without Terminal Value	2,102.7	NPV without Terminal Value	831.8	NPV without Terminal Value	1,270.8
		NPV of Terminal Value	217.5	NPV of Terminal Value	23.7	NPV of Terminal Value	193.8
		Terminal Value as % Total NPV	9.4%	Terminal Value as % Total NPV	2.8%	Terminal Value as % Total NPV	13.2%
		Total NPV	2,320.1	Total NPV	855.5	Total NPV	1,464.7
		Probability-Weighted NPV	428.2	Probability-Weighted NPV	213.5	Probability-Weighted NPV	214.7
		NPV as % of Total NPV		NPV as % of Total NPV	36.9%	NPV as % of Total NPV	63.1%
		NPV as % of Prob-Weighted NPV		NPV as % of Prob-Weighted NPV	49.9%	NPV as % of Prob-Weighted NPV	50.1%

Royalty Structure							Step-down	
Choose method from drop-down be	Territory	Tier 1 Royalty	Tier 2 Royalty Threshold	Tier 2 Royalty Rate	Tier 3 Royalty Threshold	Tier 3 Royalty Rate	Year	Rate
Tiered	United States	16.0%	100	17.0%	350	20.0%	2029	8.0%
	Europe	16.0%	100	17.0%	350	20.0%	2029	8.0%
	Japan	16.0%	100	17.0%	350	20.0%	2029	8.0%
	ROW	16.0%	100	17.0%	350	20.0%	2029	8.0%

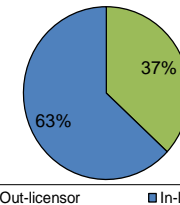
Net Cash Flow



Risk-adjusted Net Present Value



Total Net Present Value



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.

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CASE STUDY – until 12:30

LUNCH – 12:30 – 13:30

Today's Program

08:30 **Valuation and Deal Structuring Concepts and Trends**

09:45 *Break*

10:00 **Valuation Tools and Techniques**

11:00 *Case study work*

12:30 *Lunch*

13:30 **Forecasting and Market Analysis**

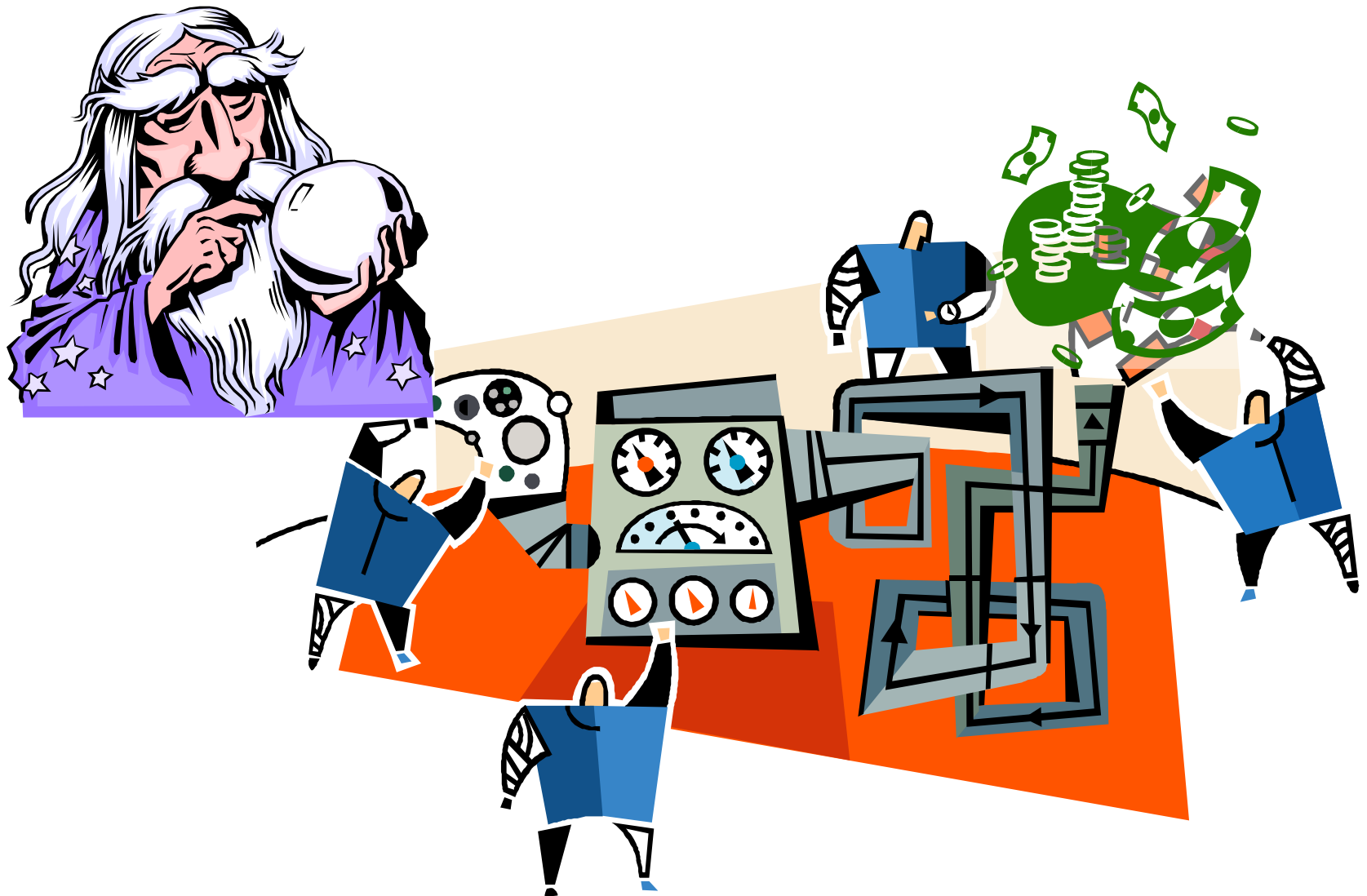
14:30 *Case study work (and break)*

16:00 **Value Sharing and Deal Terms Structuring**

17:00 *Program Concludes*

17:30 **Networking Reception**

The Optimist's Forecasting Process



Major Revenue Forecasting Considerations

Patient Based

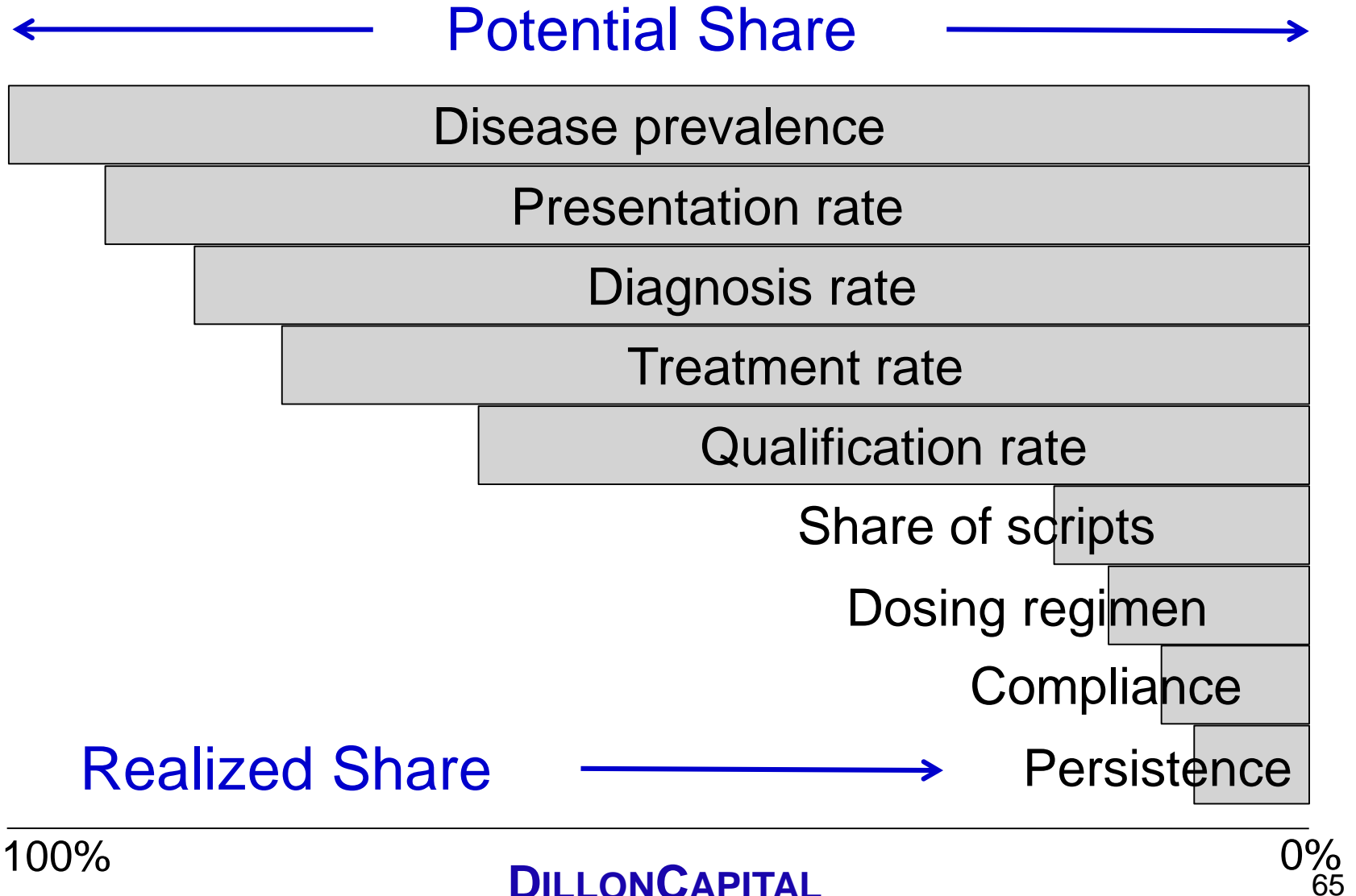
- Epidemiology - Prevalence, incidence and patient flow
- Treatment protocol - Doctor's preference and requirements
- Dosing regimen
- Compliance and persistence

Market Based

- Competitive set
 - 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



Example Models

We'll spend a few minutes here to walk through a few example revenue forecasts.

Reconciling Market and Patient Basis

Expected usage
based on treatable
population



Usage based on
audited sales data

□ Possible causes

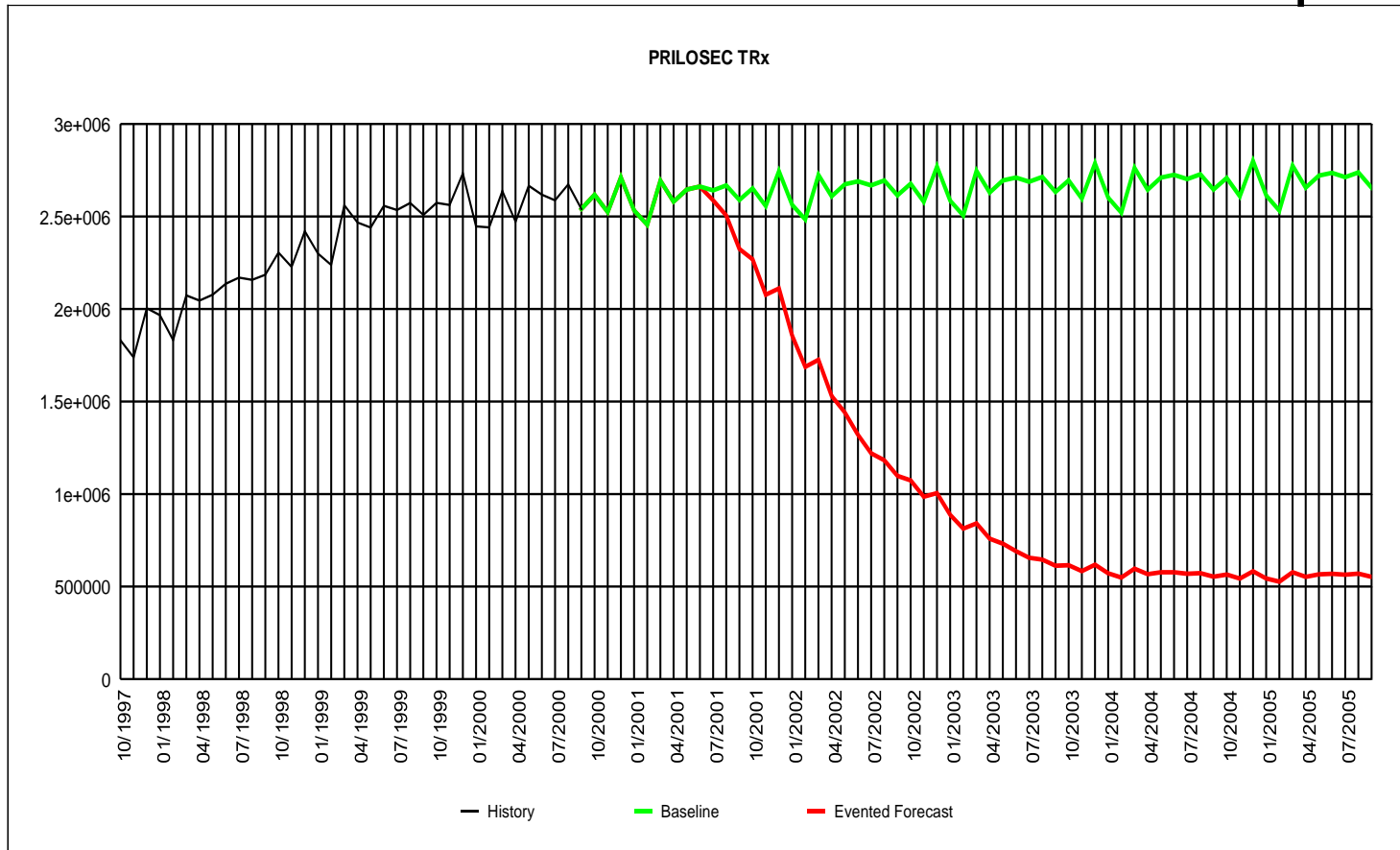
- Inaccurate epidemiology data
- Miscalculated patient flow
- Misunderstood usage
- Inaccurate sales audit data
- Wrong sales audit data pulled

Trending and Eventing

- **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 - taking the future into account:** fitting curve into the future, being informed by historical data on comparable products. Example events:
 - Loss of patent or exclusivity protection – Your product or competitor’s
 - Changes in pricing and/or reimbursement strategy or policy
 - Exit of competitor(s)
 - Entrance of competitor(s)
 - Product goes over-the counter (OTC) – Yours or competitor’s
 - Labeling change of product (e.g. dosing or “black box”)
 - Additional indications (be sure to include R&D and risk)

Trend Breaking

Curve fitted + evented forecast example



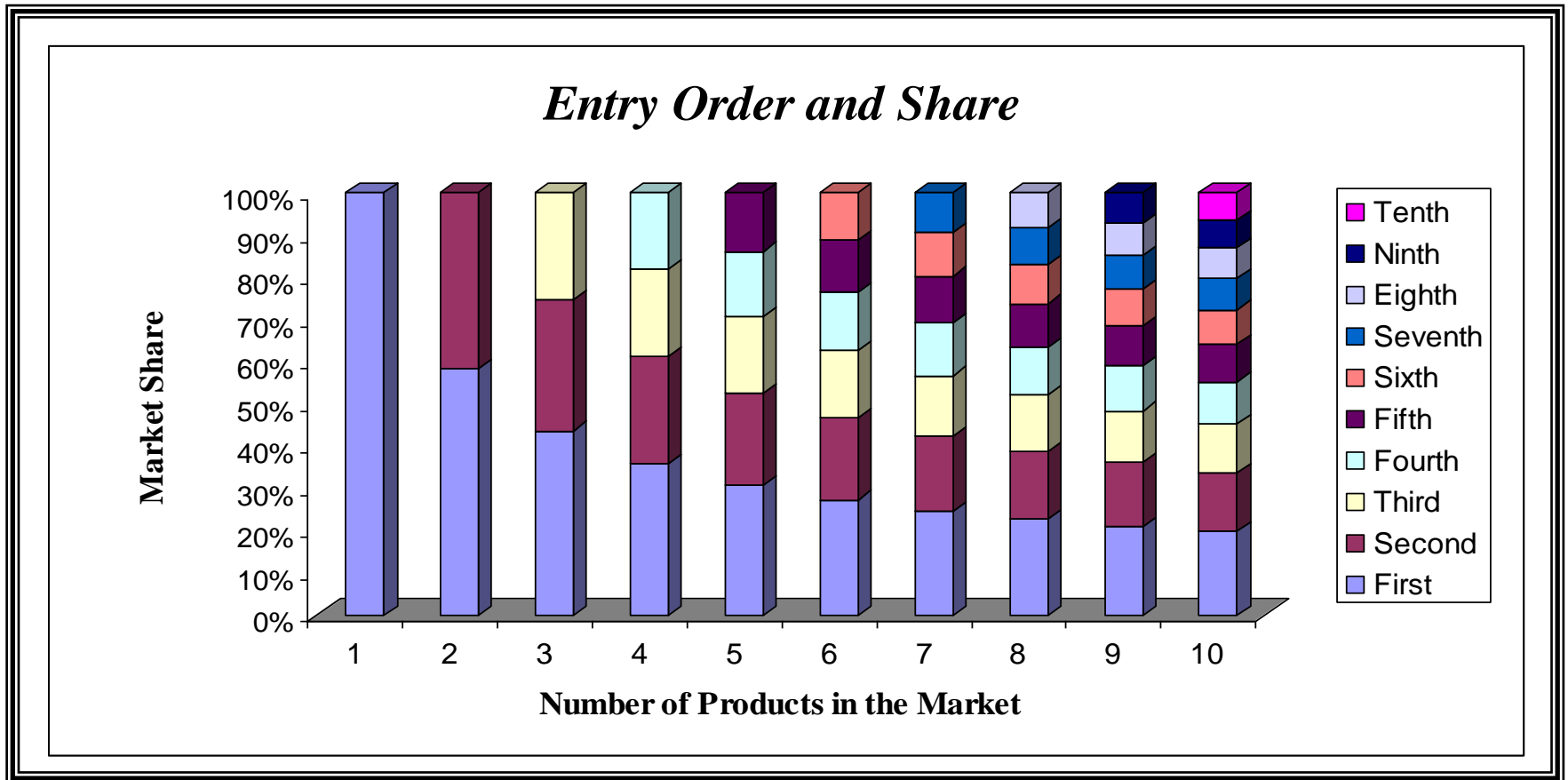
Analogs or Comparables

- ❑ The key to “event-based” forecasting is the use of analogs (i.e. 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

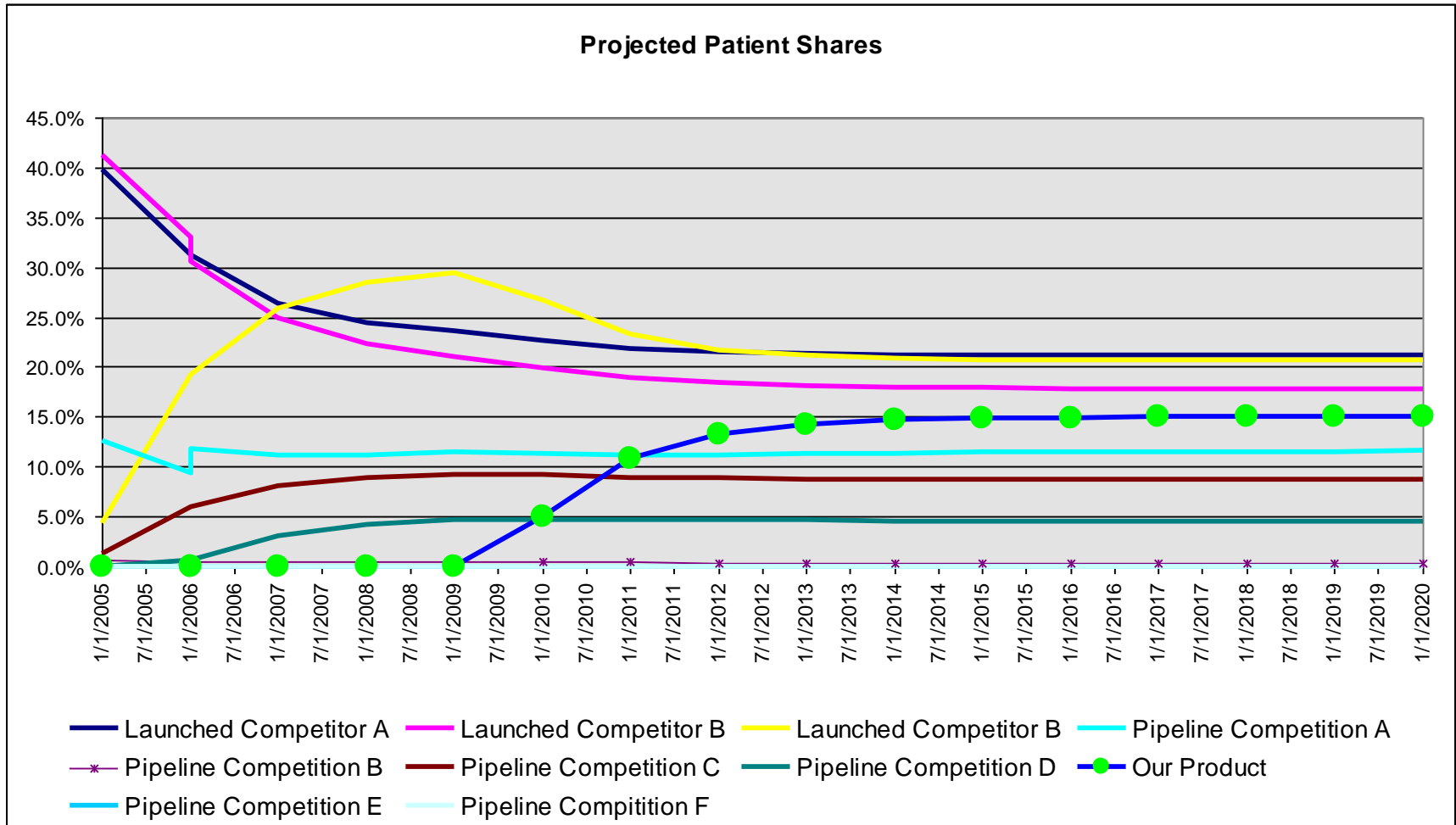
- ❑ Competitors can expand a market as well as compete for market share
- ❑ Include pipeline products as well as marketed products in competitive analysis
- ❑ Major considerations are:
 - Product profile (mechanism of action, efficacy, safety, side effects, dosing)
 - Indications obtained / likely to 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

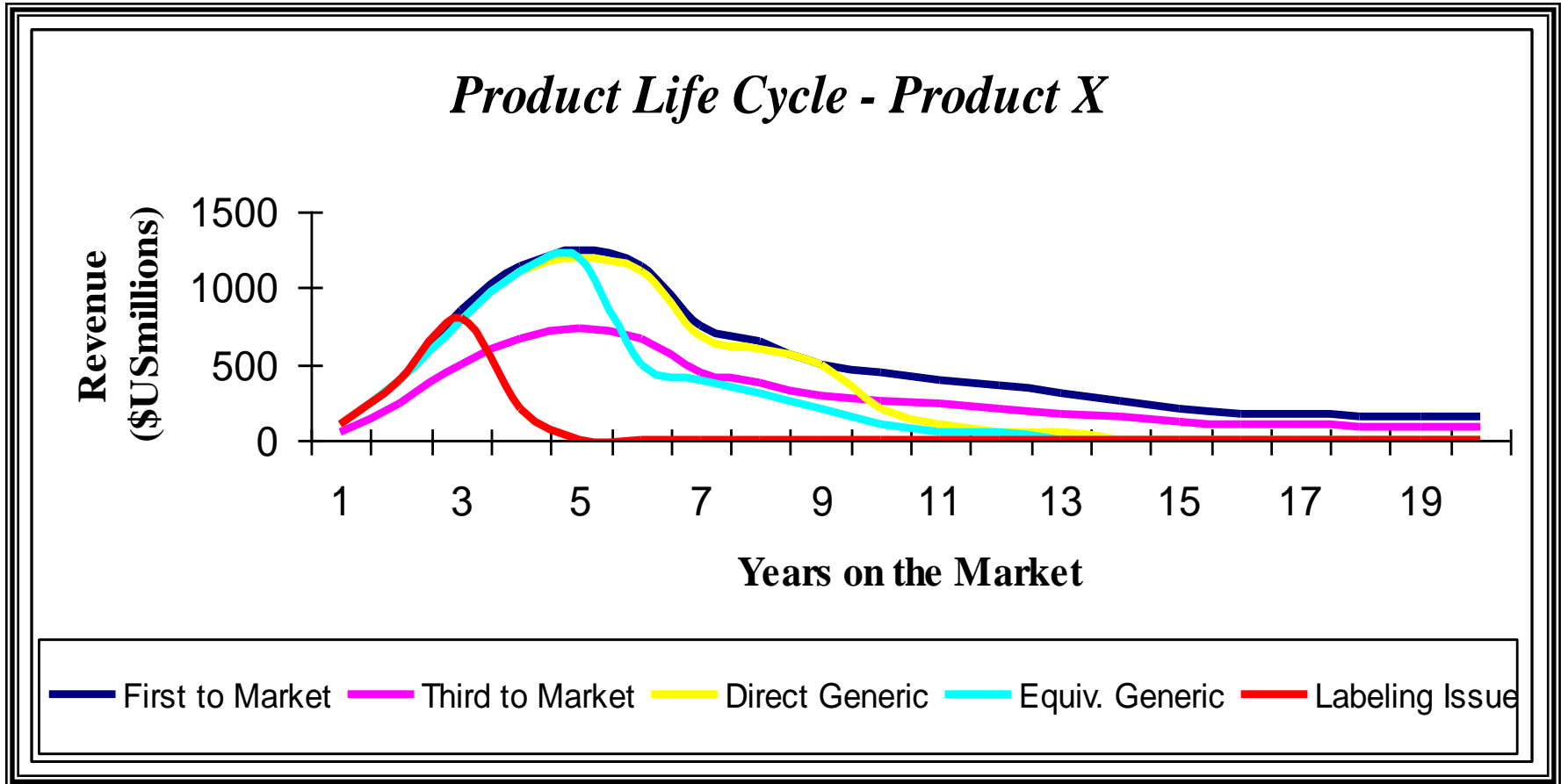


Many market variables can influence share

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

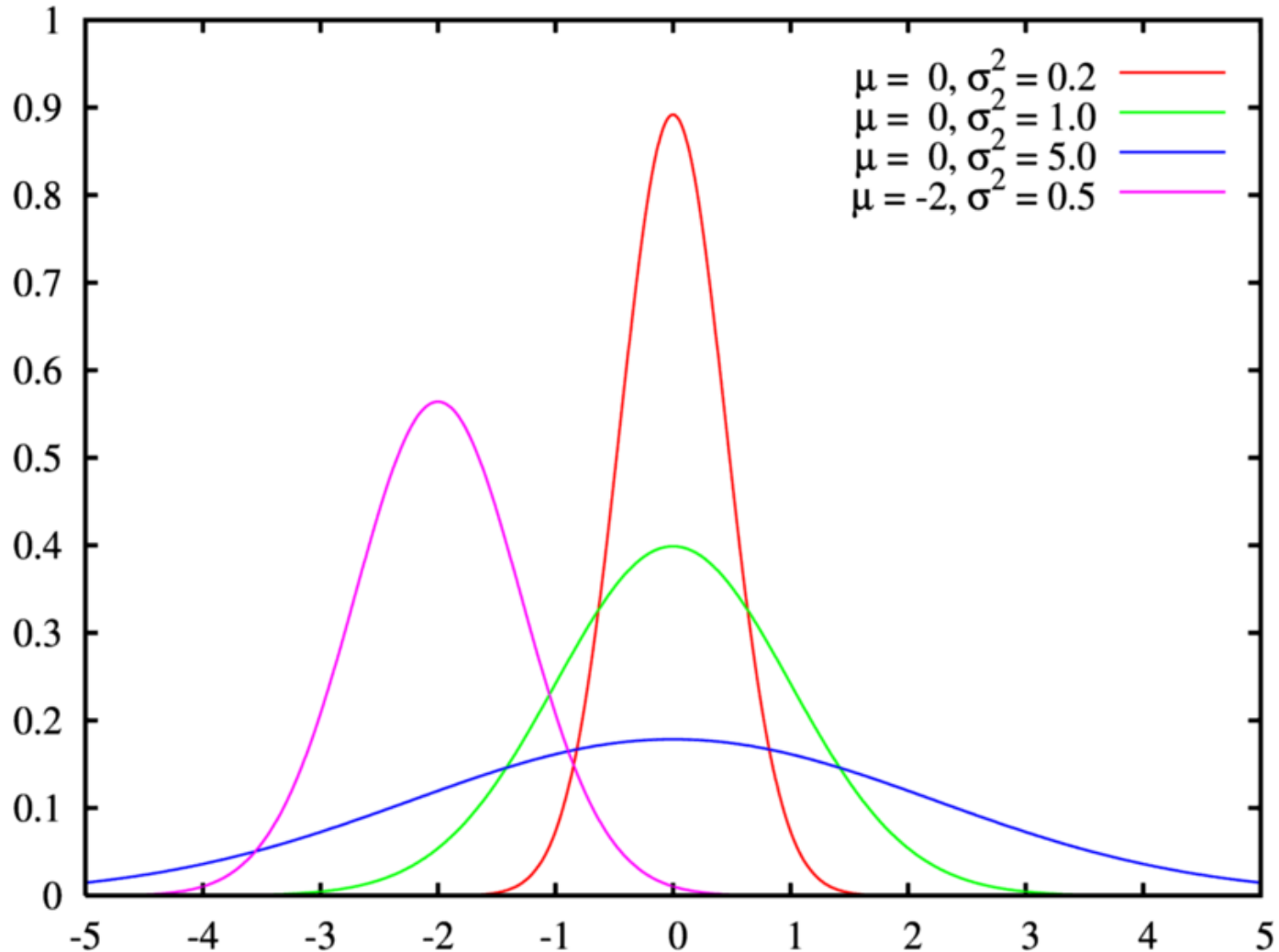
❑ How do you do it?

- 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

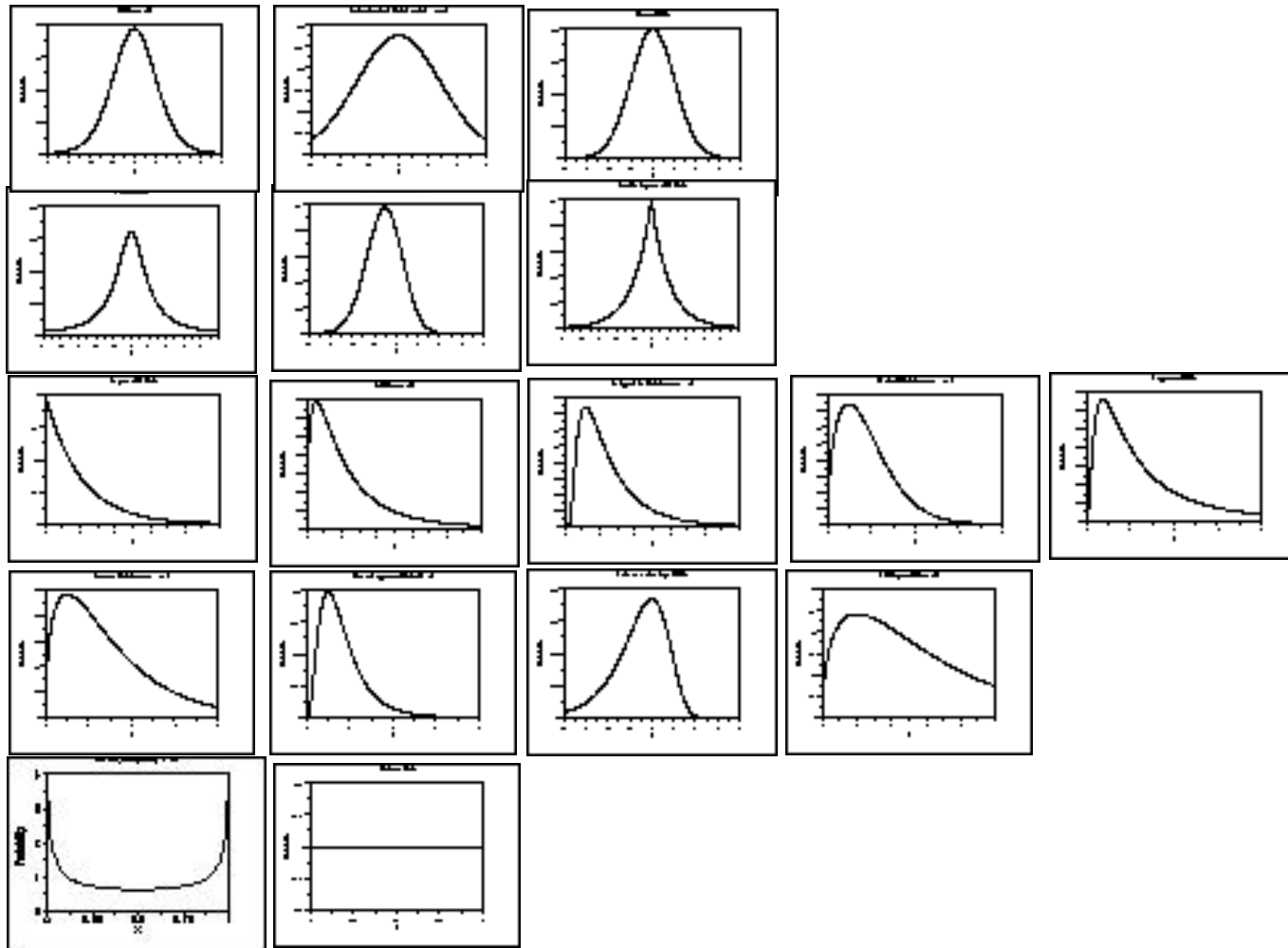
Advanced Simulation Tools – Monte Carlo

- 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?

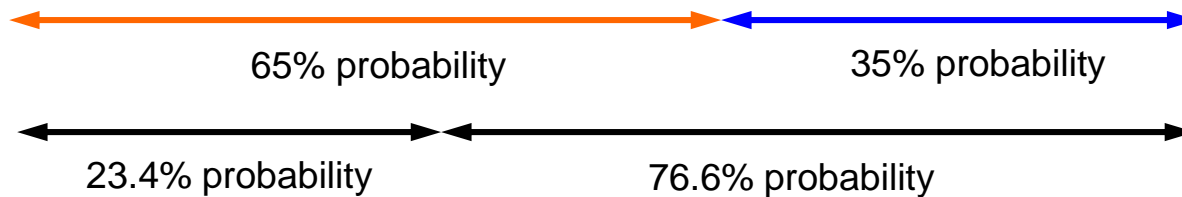
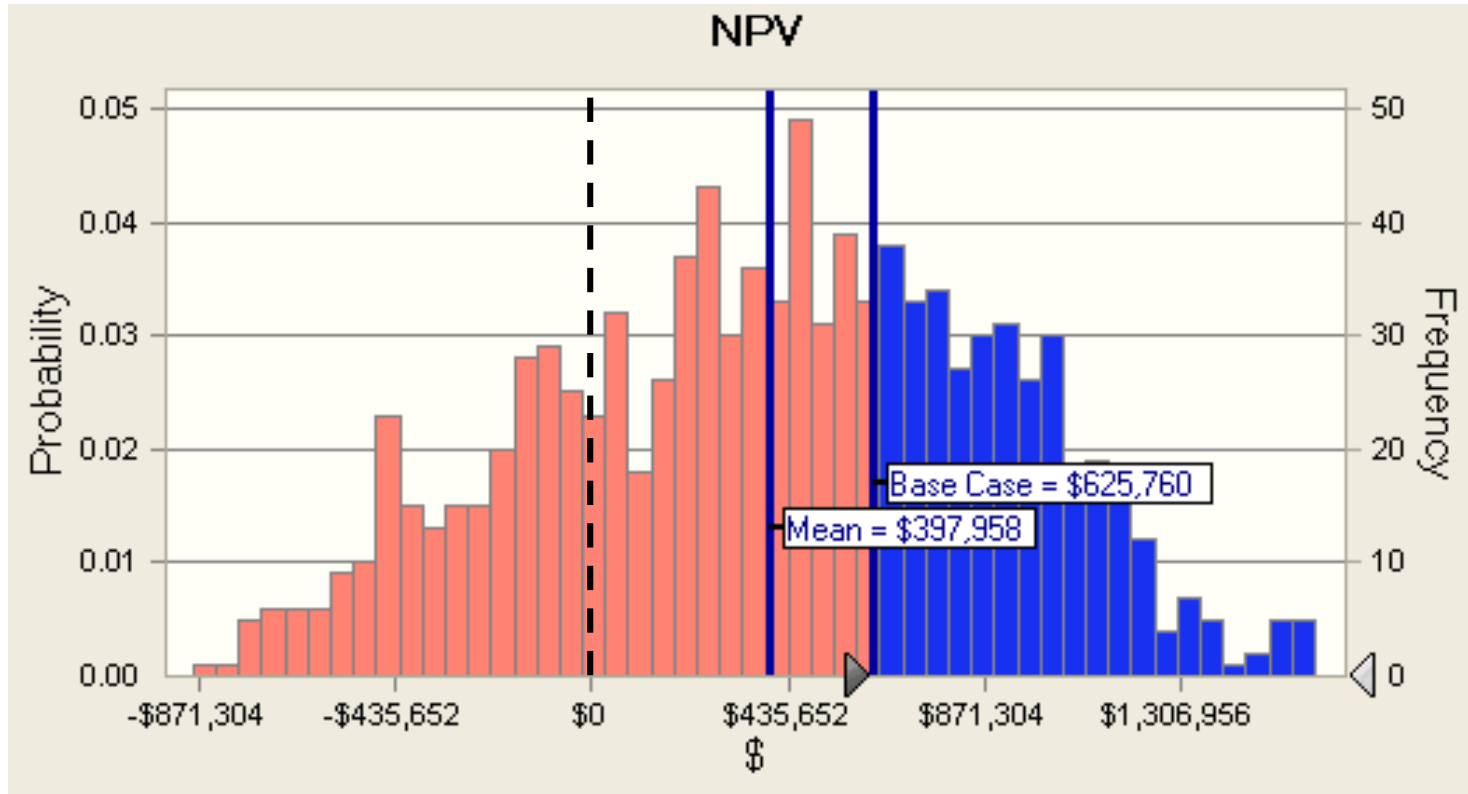
Monte Carlo Distribution Curves



Monte Carlo – A Few More Curves



Monte Carlo Simulation Example



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

On Getting Real

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



— CT Jones

Case Study Work and Break!

(return at 4:00pm)

Today's Program

08:30 **Valuation and Deal Structuring Concepts and Trends**

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 *Program Concludes*

17:30 **Networking Reception**

The Art of the Deal

- ❑ A 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
- Tiered royalties based on revenue, margin or some other metric
- Agreeing who pays “reach-thru” or “stacked” (legacy) royalties due

Manufacturing payments

- Transfer price profit
- Cost plus mark-up, % of resale price or other such method

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

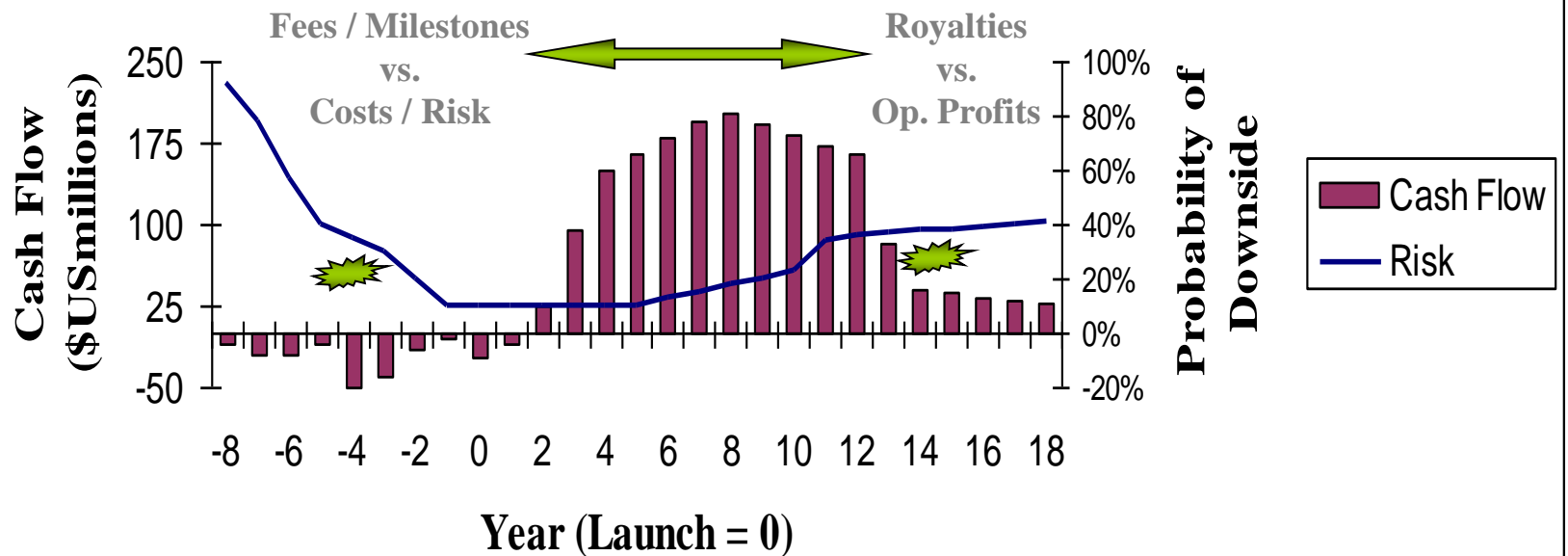
Widely Known Deal Terms' Usage

□ Usage of Widely Known Deal Terms

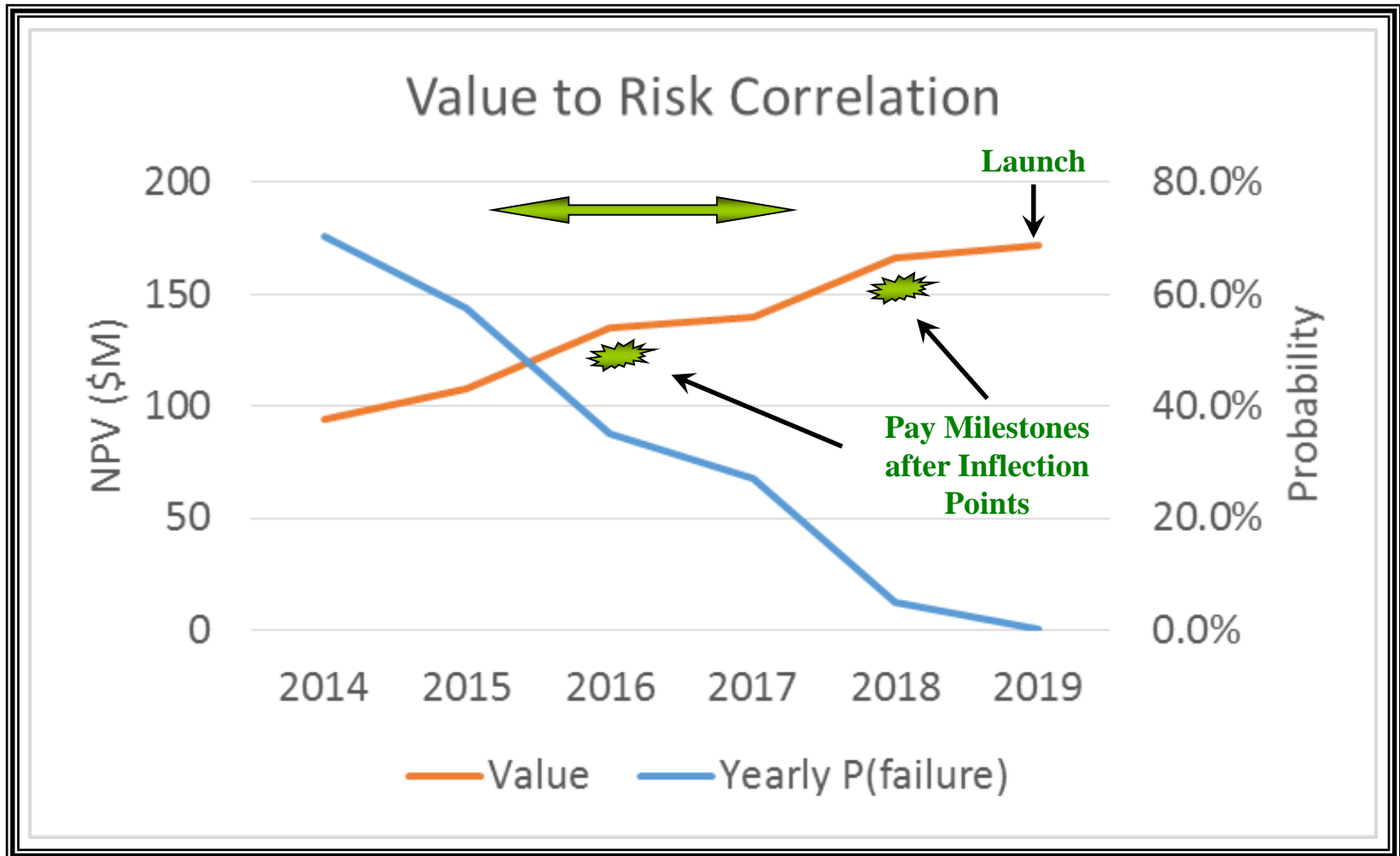
- **Upfront** – common and highly dependent upon risk and asset value
- **Development Milestones** – common with higher use in earlier stage deals, also dependent on risk and value
- **Royalties** – common and somewhat more likely a fixed rate, but more are tiered for early stage deals, almost always based on net sales
- **Co-development** – more common in very early stage, far less common in later stage deals
- **Co-promotion** – not common, unless sell-side is already established in a region
- **Territory** – Far more common to be global or multi-regional
- **Field** – most likely all potential uses for the asset within a therapeutic area
- **Profit-sharing** – not common
- **Commercial Milestones** – very common, especially in earlier stage deals, sometimes exceeding the total of all development milestones

How Much to Pay and Deal Structuring?

Cash Flow vs Risk



Inflection Points



Example Deal

Anatomy of a Drug Candidate Licensing Deal

□ Opportunity:

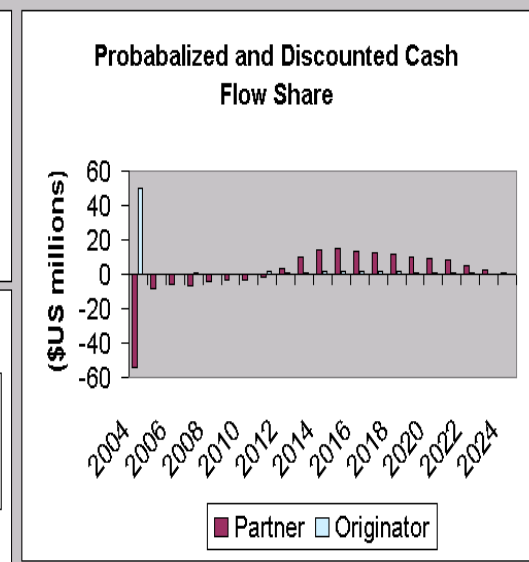
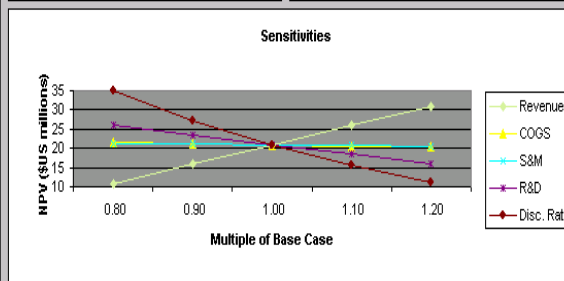
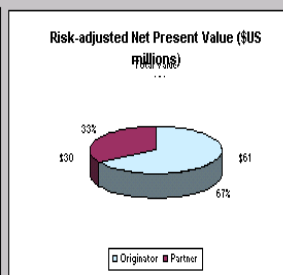
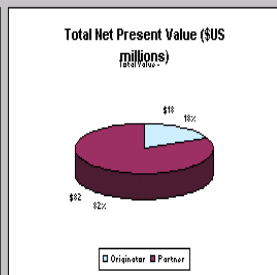
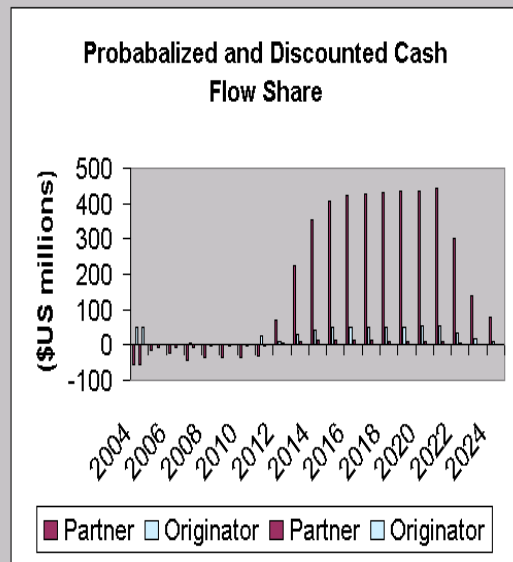
- | | |
|---------------------------|---------------|
| ▪ Stage of Development | Pre-clinical |
| ▪ Probability of Launch | 11% |
| ▪ R&D | \$284 Million |
| ▪ Launch Year | 2012 |
| ▪ Forecast Peak Net Sales | \$808 million |

□ Proposed Deal:

- | | |
|-------------------------------|--------------|
| ▪ Licensee (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%	<i>Royalty Scheme</i>		<i>Scenario Multiples:</i>		<i>Scenario</i>	<i>Milestones</i>			
Nominal Discount Rate	13.40%			Sales	1.20	<input checked="" type="checkbox"/>	Upfront Fee	50.00	<input checked="" type="checkbox"/>	
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	<input checked="" type="checkbox"/>
Working Capital as % Revenue	-15.0%	Range 3	10%	500	Research & Development	1.00	Three	United States NDA approval	50.00	<input checked="" type="checkbox"/>
Terminal Value Growth Rate	-5.0%				Other Operating Expenses	1.00	Four	Cummulative revenue of \$1 billion in US	0.00	



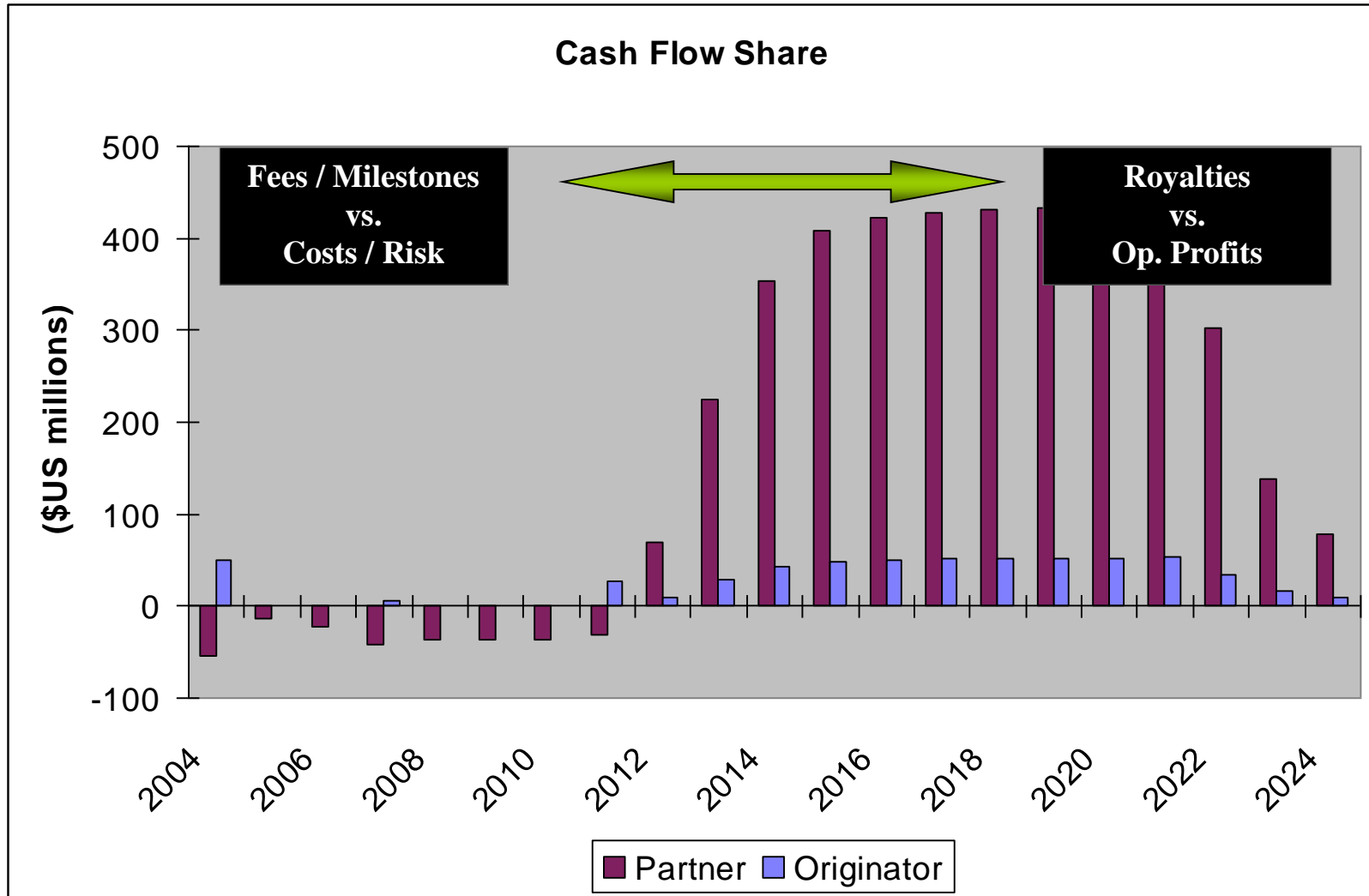
Value Components	Total Product Value				Value Components	Value to Originator				Value Components	Value to Partner			
	Consolidated	Area				Consolidated	Area				Consolidated	Area		
		United States	Major Europe	Canada			United States	Major Europe	Canada			United States	Major Europe	Canada
NPV without Terminal 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
Probability-Weighted NPV	91.2	58.6	28.4	4.2	Probability-Weighted NPV	60.8	37.8	19.7	3.3	Probability-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	NPV = 181.6	50.0	-	-	6.6	-	-	-	26.4	9.8	28.2	43.2	49.1
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	NPV = 1,001.5	(4.5)	(13.4)	(22.3)	(35.6)	(35.6)	(35.6)	(35.6)	(4.5)	79.4	252.6	397.4	457.4

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

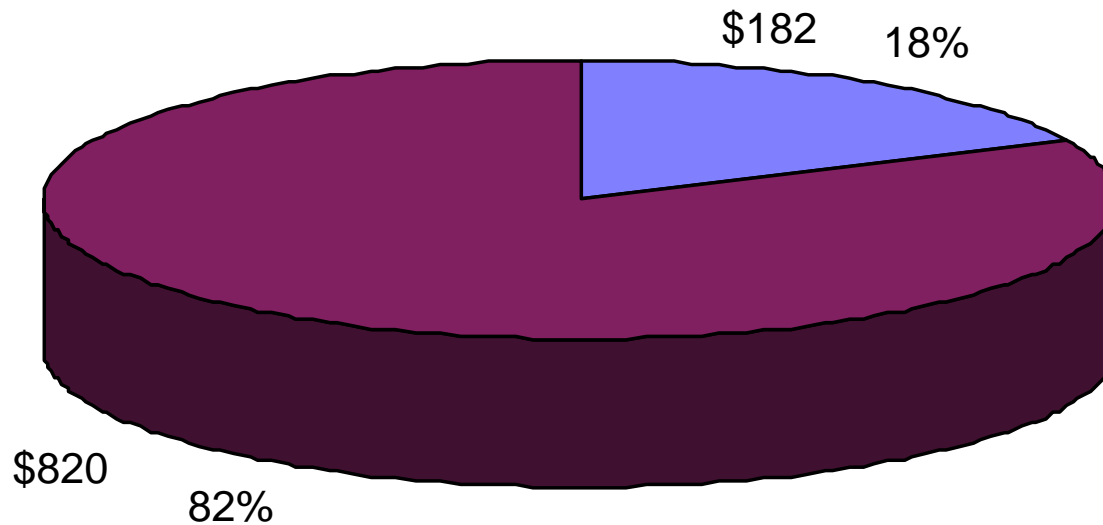
Partner's Cash Flow Timing



Resulting Shares of the Pie

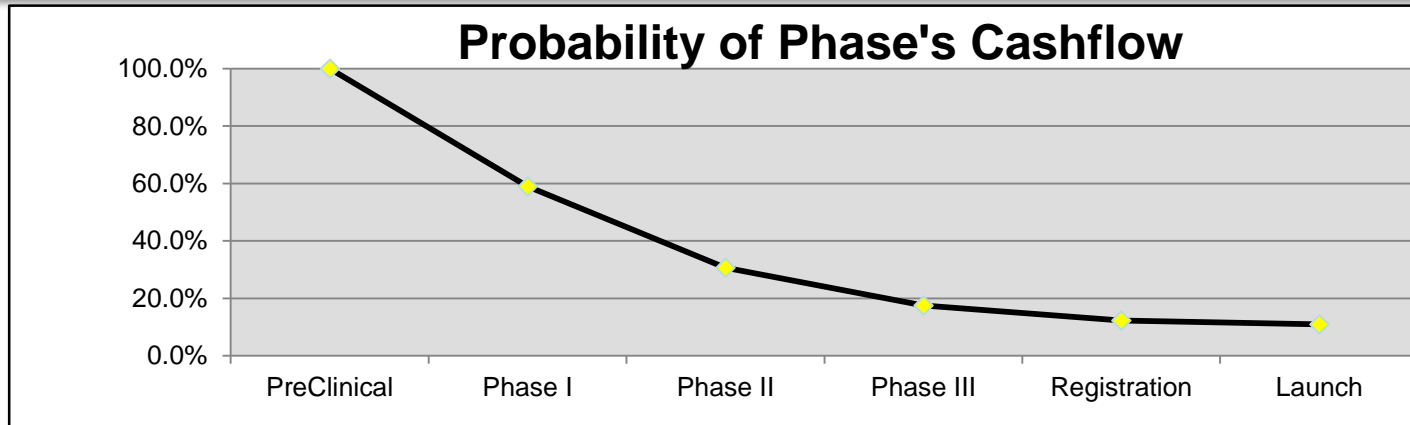
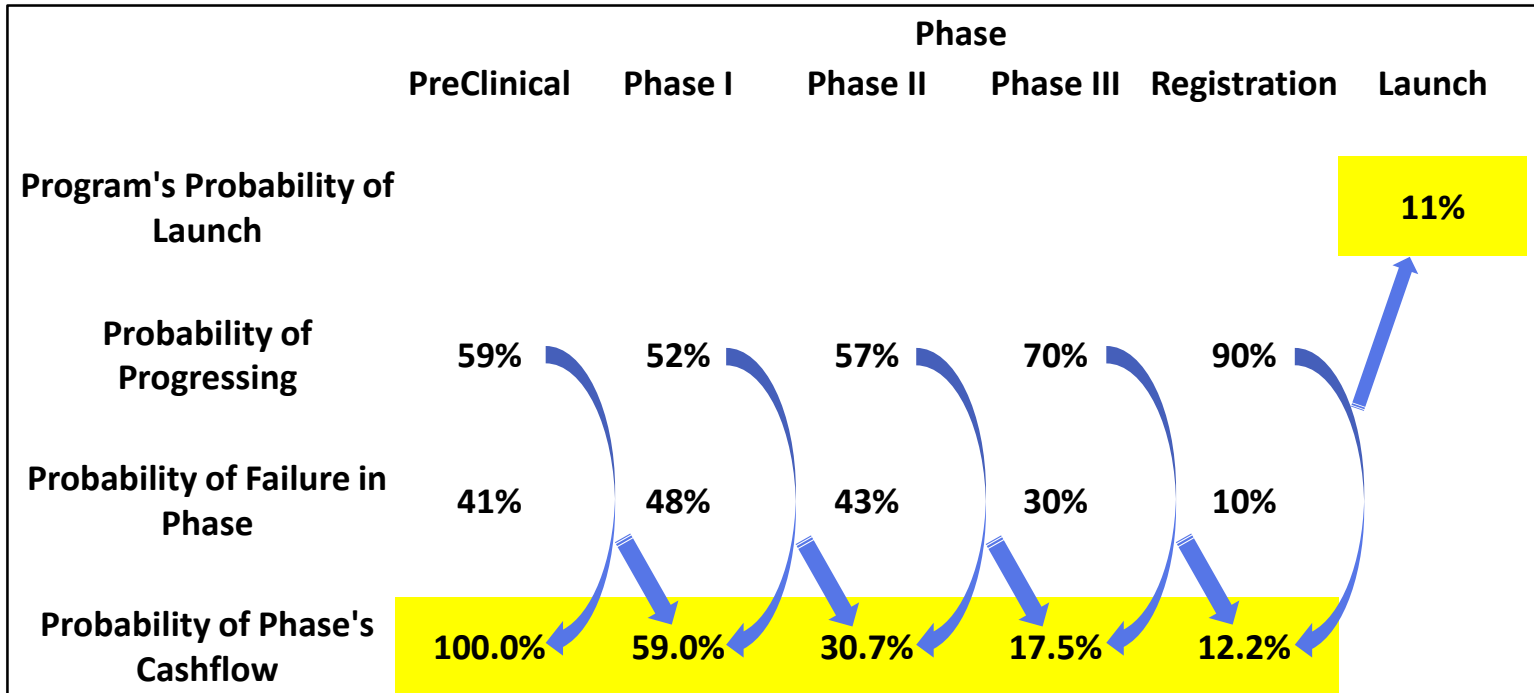
Total Net Present Value (\$US millions)

Total Value = \$1002

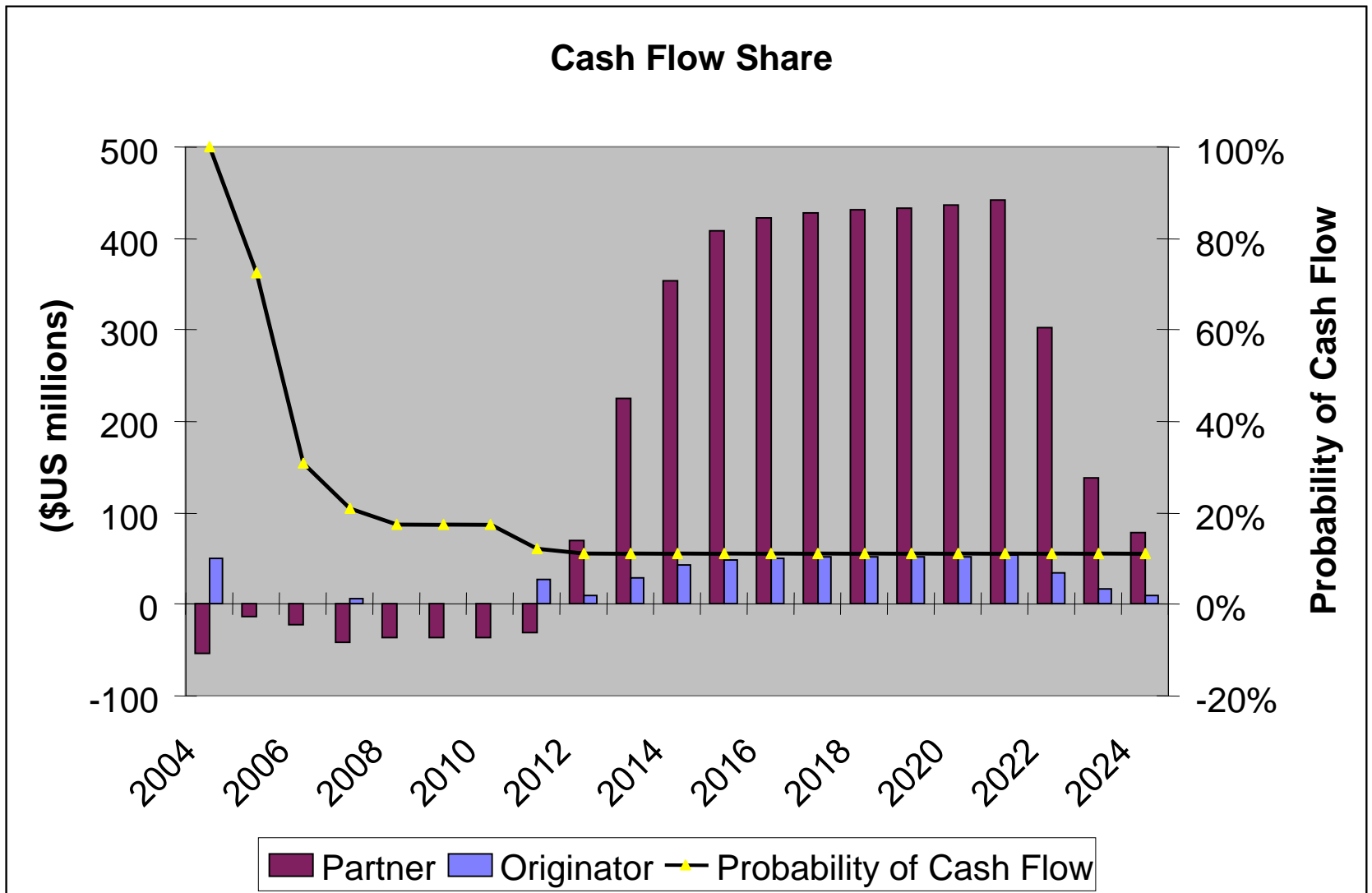


■ Originator ■ Partner

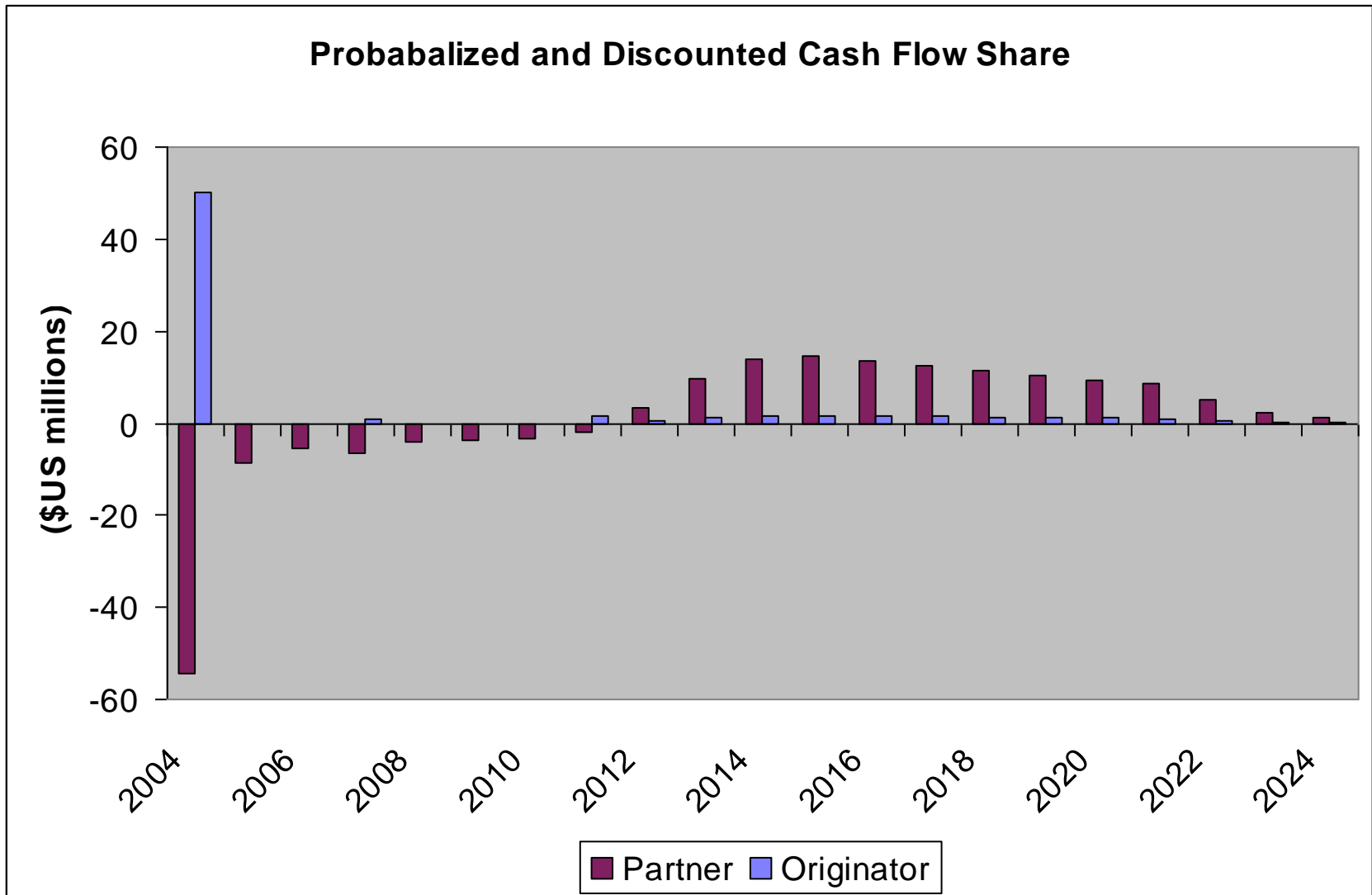
Investment and Milestone Risk Gaming



Risk and Value Sharing



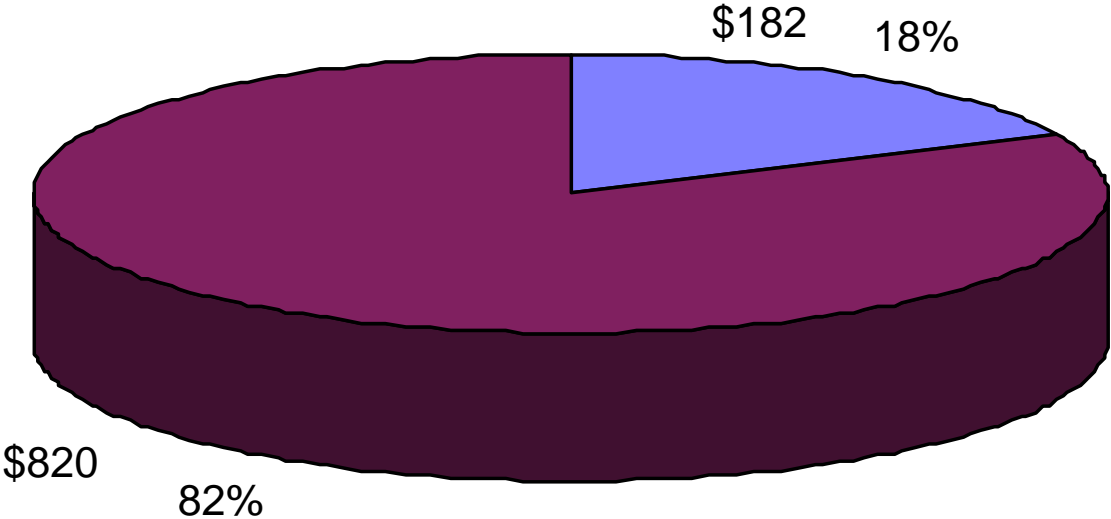
Adjusted Value Sharing



Shares of the Pie – Simple Method

Total Net Present Value (\$US millions)

Total Value = \$1002

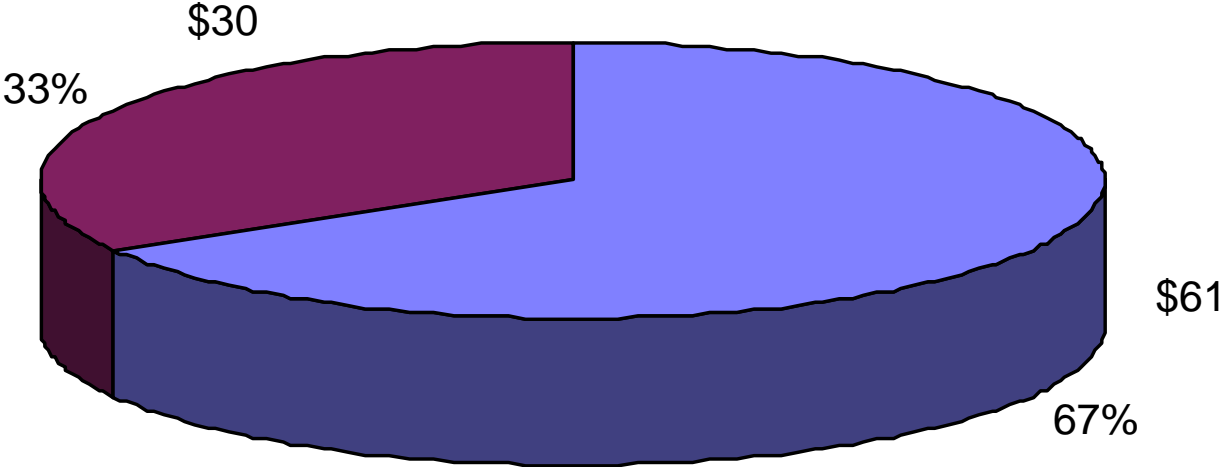


■ Originator ■ Partner

Resulting Shares of the Pie – Phased Method

Risk-adjusted Net Present Value (\$US millions)

Total Value = \$91

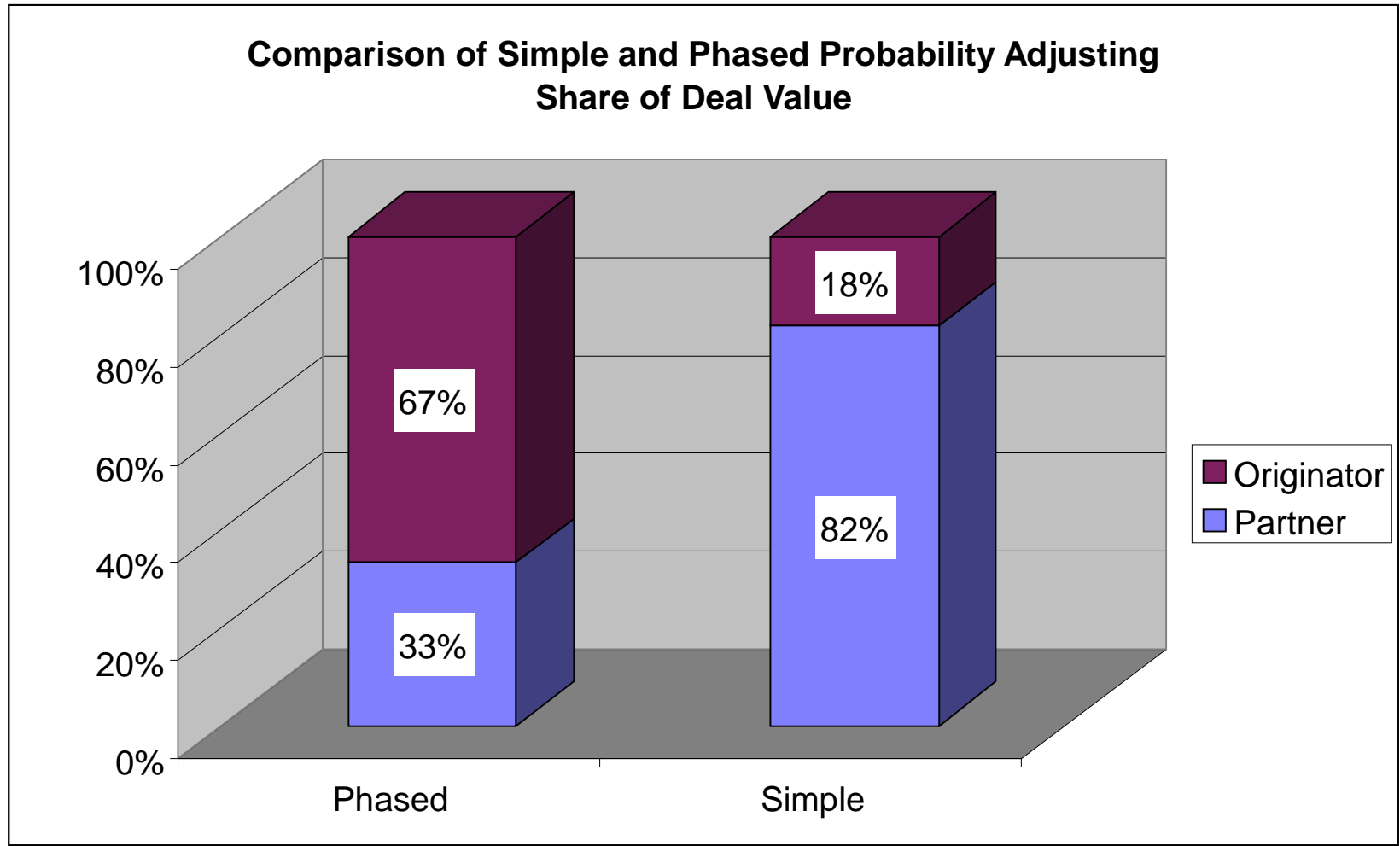


■ Originator ■ Partner

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

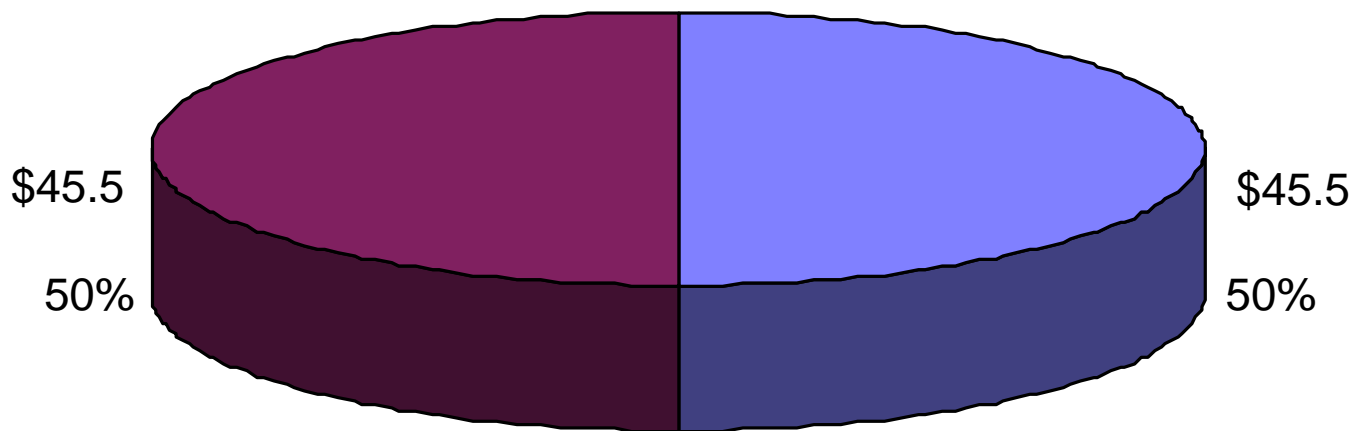


Impact of Changing Fees and Milestones

Risk-adjusted Net Present Value (\$US millions)

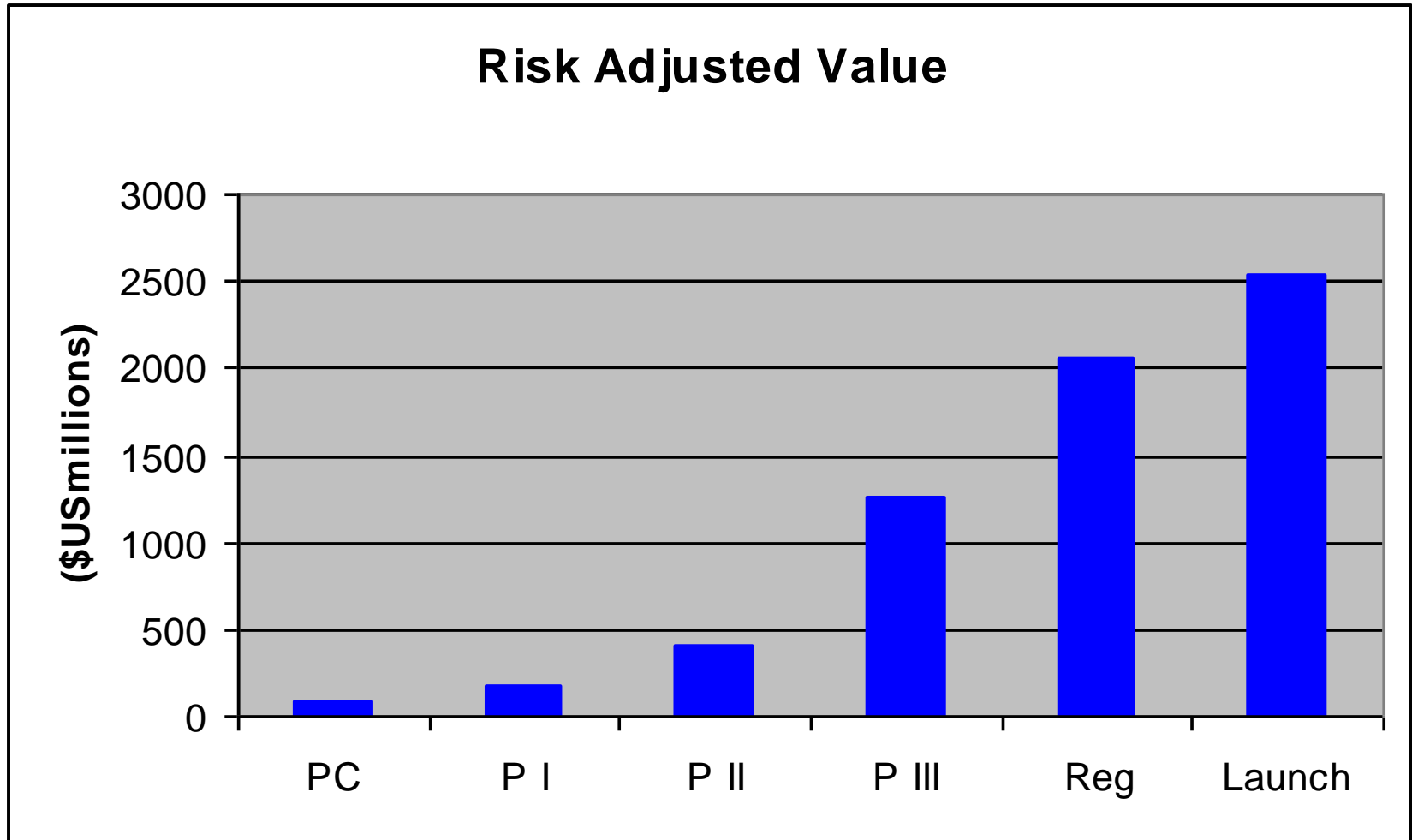
Total Value = \$91

Moved \$18MM from Upfront to Phase III milestone
and reduced launch milestone to \$20MM

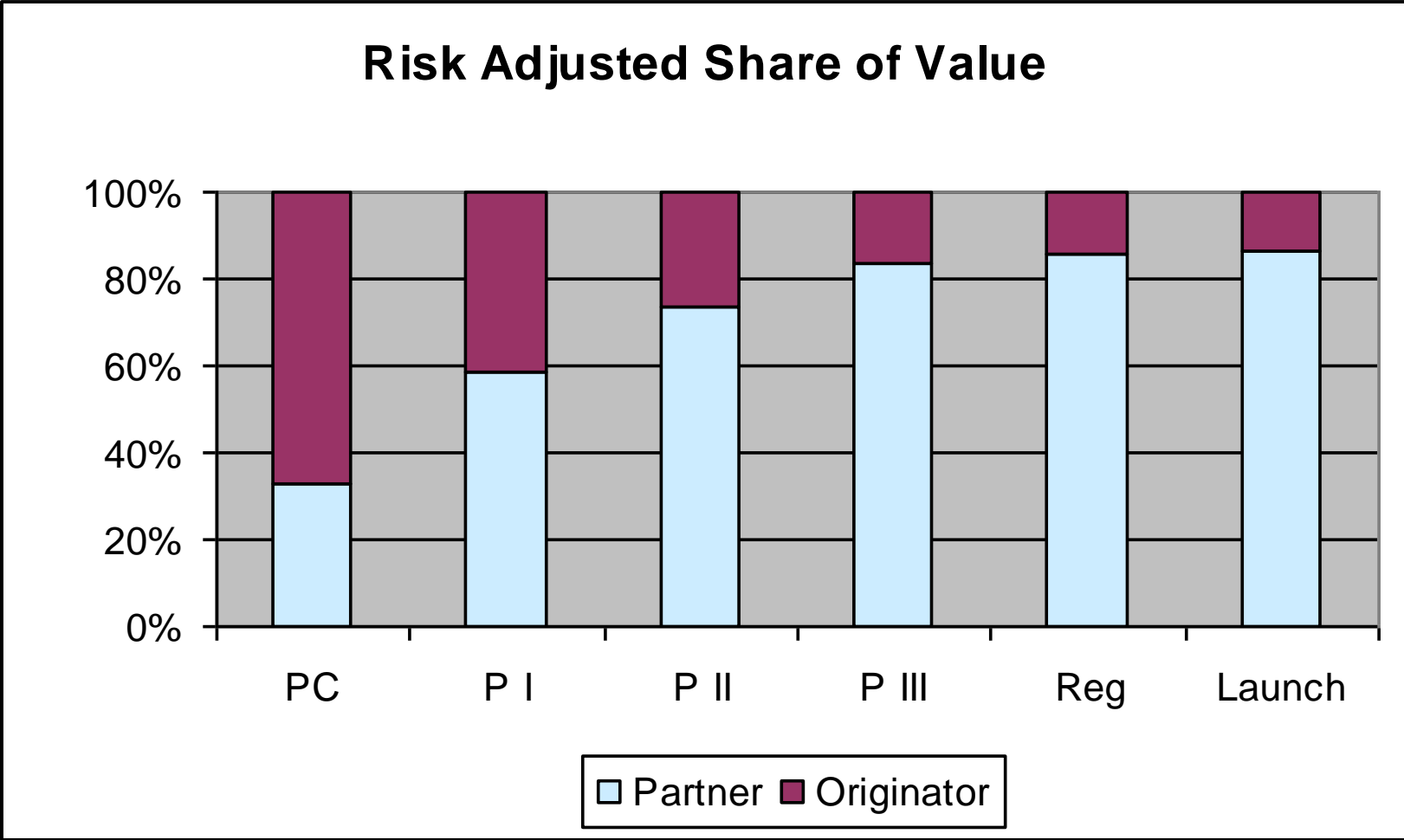


■ Originator ■ Partner

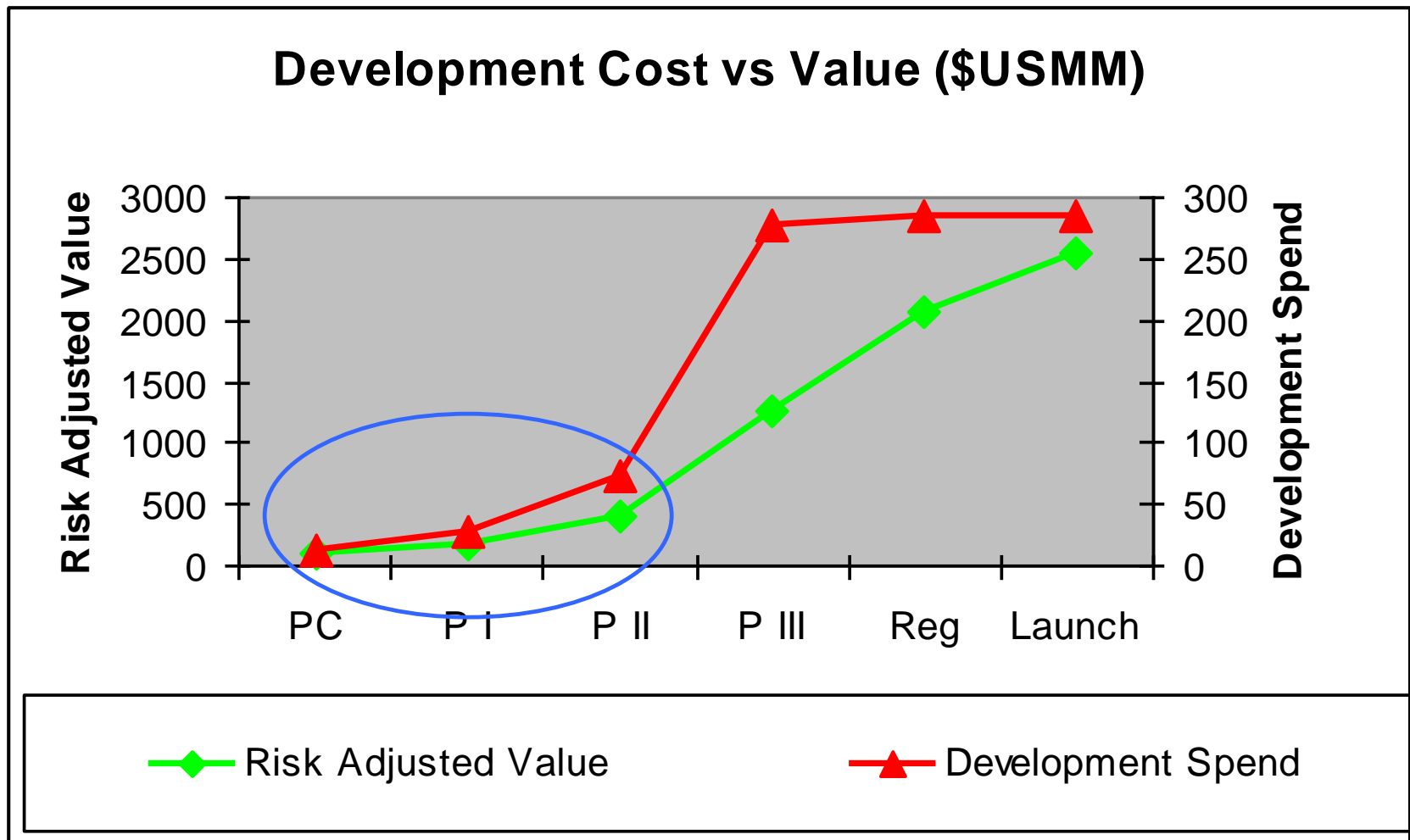
Value Adding



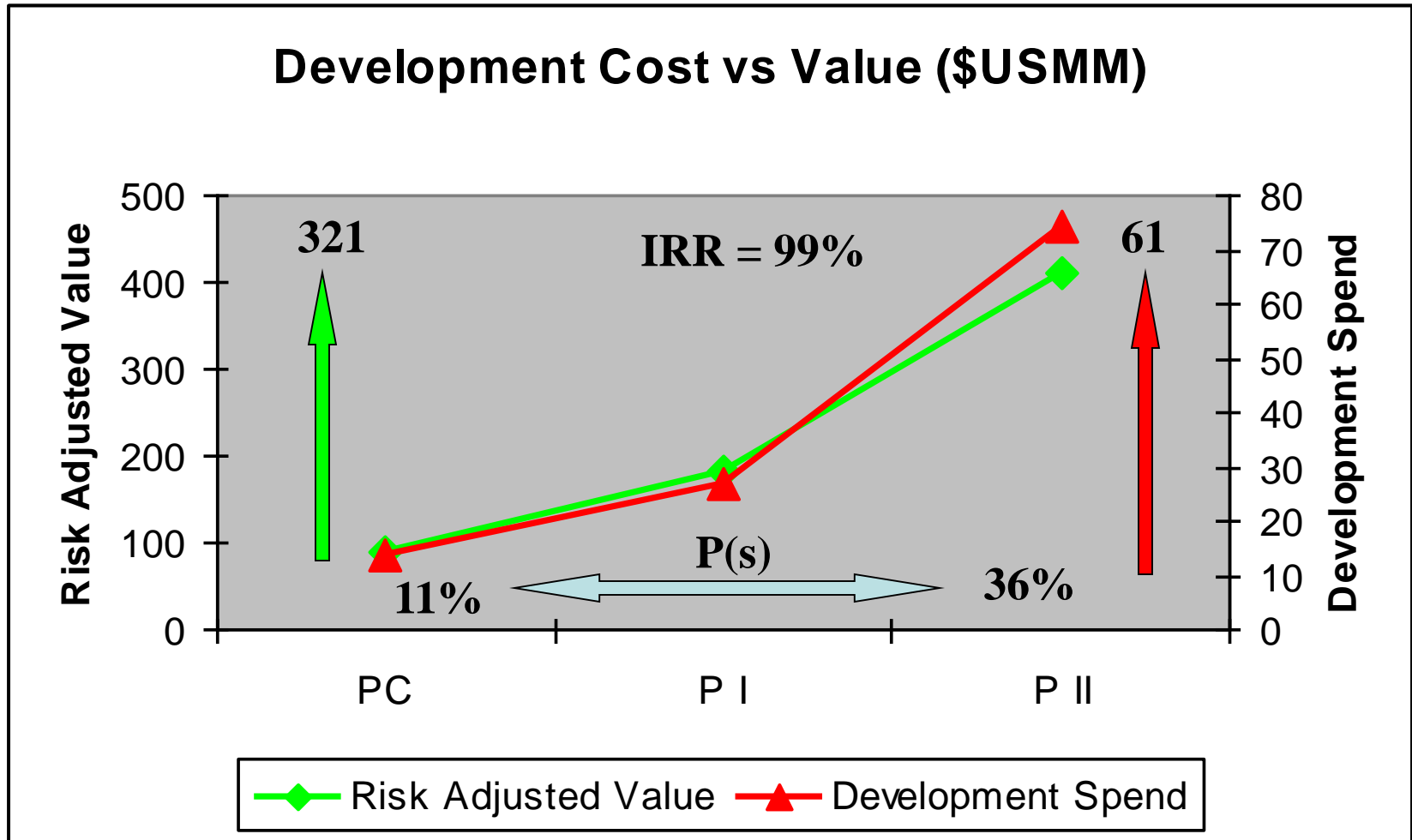
Partnering Timing - Shifting Value Shares



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 poorly understood variables
- Important variables sometimes arbitrary
- May not simulate the situation at hand – “the model doesn't do that”
- Scenario testing can be time-consuming
- May not be able handle risk adjusting
- User may be inexperienced – “....but the model says.....”
- Formula errors can lurk without being noticed

Finer Points of Deal-making

□ Adjusting Deal Structure to bridge disconnects

- Cost of Capital
- Probability of success
- Timing of achievements
- Revenue (units, price, lifecycle)
- Terminal Value
- Costs & Expenses
- Performance
- Cash needed is less than value
- Out-licensor wants to develop
- Out-licensor wants to market

Cost of future capital to be invested

Upfront, milestones & options

Milestones, options

Royalty rate & “bonus” payments

Term, royalty tier, option

Definitions, limits, sharing

Definitions, limits, bonus payments

M&A, equity stake, loans

R&D subsidies, staff sharing

Profit share, S&M share, splits

Remember - It's Not Just the Math

“Beware of geeks bearing formulas.”



— Warren Buffet

Thank You !

Joe Dillon
President

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