A Word from the Attorneys

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“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
Before We Get Started

- Your colleagues here – Know them & learn from them
- People’s expertise differ – Be patient and grow
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

You are part of the learning experience here
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- **The model** – Essential, but its not just the math

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- Timing – Keep moving, no analysis paralysis
- Checkpoints – Make goals and observe checkpoints
  - Today
  - Tomorrow
  - Last day

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- **Case study solution** – there is no one correct answer

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- 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

- **Small pharma** – 1996 to 2003. Positions of CFO, COO, CEO and Board member.
- **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.
Multiples are a result, not a tool.
Deal Trends

- **Number of Biotech Out-licensing Deals** – Pipeline acquisitions and alliances trending down 50% since 2006.


- **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-tooos” 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

2000

- Contingent
- Fixed
Game-changing Deal Structure Trend
Game-changing Deal Structure Trend

2000

- Contingent
- Fixed

Current

- Contingent
- Fixed
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 streams and other valuable consideration which the parties agreed not to make the monetary value of public.
"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.
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!
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%
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
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
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.
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

Opportunity Analysis and Negotiation Team

Strategic Planning & Business Development
Manufacturing Operations
Sales and Marketing Strategy
Executive Sponsorship
Parent Company & Affiliate Operations
Research and Development
Finance and Accounting
Legal and Regulatory

DILLON CAPITAL STRATEGIES
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
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!
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

\[ E = \text{I} + (\text{M} - \text{I}) + \text{S} + \text{IP} = \]

<table>
<thead>
<tr>
<th>Component</th>
<th>Value</th>
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<tbody>
<tr>
<td>Return for a specific Investment</td>
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</tr>
<tr>
<td>Risk-free rate</td>
<td>I 3.32%</td>
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<tr>
<td>Return for the equity market as a whole</td>
<td>M 10.72%</td>
</tr>
<tr>
<td>Market risk premium</td>
<td>(M - I) 7.40%</td>
</tr>
<tr>
<td>Small company/Liquidity premium</td>
<td>S 0.00%</td>
</tr>
<tr>
<td>Industry Premium</td>
<td>IP 4.00%</td>
</tr>
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</table>

**Total Cost of Equity Capital** 14.72%
**Rounded Cost of Equity Capital** 14.7%

#### Weighted Average Cost of Capital (WACC)

\[(\text{IRR Debt} \times (1 - \text{Tax Rate}) \times \text{Debt:Capital Ratio}) + \text{IRR Equity} \times \text{Equity:Capital Ratio}\]

<table>
<thead>
<tr>
<th>Component</th>
<th>Value</th>
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<tr>
<td>IRR Debt</td>
<td>7.90% Baa bond yield</td>
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<tr>
<td>Average Tax Rate</td>
<td>38.00%</td>
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<tr>
<td>Average Debt:Capital Ratio</td>
<td>4.00%</td>
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</table>

**WACC (Discount Rate)** 14.33%
**Rounded Discount Rate** 14.3%

**Marginal Tax Rate** 34%
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

<table>
<thead>
<tr>
<th>Period:</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<td>0.76</td>
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## Discount Rate Matters

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<td>Payments:</td>
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</table>
War-gaming Tools

Seat of the pants..............
War-gaming Weapons

...............or “heads up display”
War-gaming Weapons

.............or world domination
**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.

<table>
<thead>
<tr>
<th>First Year of Cash Flow</th>
<th>Total Product Value</th>
<th>Value to Out-licenser</th>
<th>Value to In-licensor</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Value Components</td>
<td>Consolidated</td>
<td>Value Components</td>
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<tr>
<td>Real Discount Rate</td>
<td>Nominal Discount Rate</td>
<td>8.74%</td>
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<td>Inflation Factor</td>
<td>Marginal Tax Rate</td>
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<tr>
<td>Working Capital as % Revenue</td>
<td>NPV of Terminal Value</td>
<td>10.0%</td>
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</tr>
<tr>
<td>Terminal Value Growth Rate</td>
<td>Total NPV</td>
<td>33.0%</td>
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<tr>
<td>Scenario Multiplies</td>
<td>Terminal Value as % Total NPV</td>
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<tr>
<td></td>
<td>Total NPV</td>
<td>1.671.4</td>
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<td>Total NPV</td>
<td>611.3</td>
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<table>
<thead>
<tr>
<th>Figures in: Euros (millions)</th>
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<table>
<thead>
<tr>
<th>Royalty Structure</th>
<th>Tier 1 Royalty</th>
<th>Tier 2 Royalty Threshold</th>
<th>Tier 2 Royalty Rate</th>
<th>Tier 3 Royalty Threshold</th>
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<tbody>
<tr>
<td>United States</td>
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<td>Europe</td>
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<tr>
<td>Japan</td>
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<td>17.0%</td>
<td>400</td>
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<tr>
<td>ROW</td>
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<td>200</td>
<td>17.0%</td>
<td>400</td>
<td>20.0%</td>
</tr>
</tbody>
</table>

**Calculated Royalty Rate**

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<th>Territory</th>
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<tbody>
<tr>
<td>United States</td>
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</tr>
<tr>
<td>Europe</td>
<td>12.0%</td>
</tr>
<tr>
<td>Japan</td>
<td>12.0%</td>
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<tr>
<td>ROW</td>
<td>12.0%</td>
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**Net Cash Flow**

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<tr>
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<tr>
<td>100</td>
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<td>500</td>
<td>400</td>
<td>300</td>
<td>200</td>
<td>100</td>
<td>0</td>
</tr>
</tbody>
</table>

**Risk-adjusted Net Present Value**

- Out-licensor: 50%
- In-licensor: 50%

**Total Net Present Value**

- Out-licensor: 38%
- In-licensor: 62%

**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 slice sizes. 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)
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
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  Close
Sell-side Forecasting Process
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%

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

**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
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

DTA in clinical risk adjustment

Phase I  Phase II  Phase III & Registration

\( p = 0.25 \)  \( p = 0.52 \)  \( p = 0.64 \)

\( p = 0.75 \)

\( p = 0.48 \)

\( p = 0.36 \)

Market

Fail

Fail

Fail

\( p \) values derived from data of DiMasi et al. (ibid)
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**

\[ NPV = 0 = CF_0 + \frac{CF_1}{(1 + IRR)^1} + \frac{CF_2}{(1 + IRR)^2} + \ldots + \frac{CF_n}{(1 + IRR)^n} \]

**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.

So, if \( NPV = 0 = -20 + \frac{10}{(1 + IRR)} + \frac{8}{(1 + IRR)^2} + \frac{6}{(1 + IRR)^3} + \frac{2}{(1 + IRR)^4} \), 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
**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**

<table>
<thead>
<tr>
<th>Year</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash flow, CF</td>
<td>-20</td>
<td>10</td>
<td>8</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Cumulative CF</td>
<td>-20</td>
<td>-10</td>
<td>-2</td>
<td>4</td>
<td>6</td>
</tr>
</tbody>
</table>

*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
**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

\[ S = \text{Stock Price (Present value of assets)} \]
\[ K = \text{Strike Price (Expenditure to acquire assets)} \]
\[ t = \text{Time to expiration at } T \text{ (Time decision may be deferred)} \]
\[ r = \text{Risk-free rate (Time value of money)} \]
\[ \sigma^2 = \text{Variance on return of underlying (Riskiness of project assets)} \]
The Black-Scholes equation (European Call Option)

Solution:

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

\[ d_1 = \frac{\ln\left(\frac{S}{K}\right) - \left(r + \frac{\sigma^2}{2}\right)(T - t)}{\sigma \sqrt{T - t}} \]

\[ d_2 = d_1 - \sigma \sqrt{T - t} \]

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

Terminal Value Growth Rate -5%

Terminal Value Growth Rate -25%

Terminal Value Growth Rate +5%
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 of 10% - 15% of incremental revenue.
- Our model accepts inputs expressed as a percentage and adds it as a separate line after tax.
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

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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
14:30  Case study work (and break)
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

Potential Share

Disease prevalence
Share of Market Potential

Potential Share

- Disease prevalence
- Presentation rate

100%
Share of Market Potential

Potential Share

- Disease prevalence
- Presentation rate
- Diagnosis rate

100% - 0%
Share of Market Potential

Potential Share

- Disease prevalence
- Presentation rate
- Diagnosis rate
- Treatment rate

100% 0%
Share of Market Potential

Potential Share

- Disease prevalence
- Presentation rate
- Diagnosis rate
- Treatment rate
- Qualification rate

100% 79
Share of Market Potential

Potential Share

- Disease prevalence
- Presentation rate
- Diagnosis rate
- Treatment rate
- Qualification rate
- Share of scripts

100%  0%
Share of Market Potential

Potential Share

- Disease prevalence
- Presentation rate
- Diagnosis rate
- Treatment rate
- Qualification rate
- Share of scripts
- Dosing regimen

100% 0%
Share of Market Potential

Potential Share

- Disease prevalence
- Presentation rate
- Diagnosis rate
- Treatment rate
- Qualification rate

Share of scripts
Dosing regimen
Compliance

100%

Dillon Capital
Strategies
Share of Market Potential

Potential Share

Disease prevalence
Presentation rate
Diagnosis rate
Treatment rate
Qualification rate

Realized Share
Share of scripts
Dosing regimen
Compliance
Persistence

100%  0%
Reconciling Market and Patient Basis

Possible causes

- Inaccurate epidemiology data
- Miscalculated patient flow
- Misunderstood usage
- Inaccurate sales audit data
- Wrong sales audit data pulled
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
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 1\textsuperscript{st} line, 2\textsuperscript{nd} line, etc.
  - Clinical unmet need
  - IP strength
  - Pricing / reimbursement
  - Marketer strength
  - Order of entry
Market Entry Importance

Entry Order and Share

Market Share

Number of Products in the Market

Tenth
Ninth
Eighth
Seventh
Sixth
Fifth
Fourth
Third
Second
First
Projected Patient Shares

Launched Competitor A
Launched Competitor B
Pipeline Competition A
Pipeline Competition B
Pipeline Competition C
Pipeline Competition D
Our Product
Pipeline Competition E
Pipeline Competition F

Stealing Matrix in Use
Not All Life Cycles are the Same!

Product Life Cycle - Product X

Revenue ($US millions)

Years on the Market

First to Market  Third to Market  Direct Generic  Equiv. Generic  Labeling Issue

Dillon Capital Strategies

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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
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

\[
\begin{align*}
\mu = 0, \sigma^2 &= 0.2 \quad &\text{red} \\
\mu = 0, \sigma^2 &= 1.0 \quad &\text{green} \\
\mu = 0, \sigma^2 &= 5.0 \quad &\text{blue} \\
\mu = -2, \sigma^2 &= 0.5 \quad &\text{magenta}
\end{align*}
\]
Monte Carlo – A Few More Curves
Monte Carlo Simulation Example

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
Case Study Work and Break!
(return at 4:00pm)
Today’s Program

08:30   Valuation Concepts and Discounted Cash Flow Models
09:45   Break
10:00   Valuation Tools and Techniques
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16:00   Value Sharing and Deal Terms Structuring
17:00   Close
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
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
Identifying Comparables

2000

- Contingent
- Fixed

Current

- Contingent
- Fixed
Deal Term Mix - As Announced
$100 million Deal

Milestones
50%

Upfront 50%

$100 million? When? How? What-if?
Actual Deal Terms Mix (including Royalty Payments)

- Milestones: 10%
- NPV of Royalty Payments: 80%
- Upfront: 10%

A different perspective!
Actual Deal Term Mix Probability-adjusted

- Milestones: 6%
- Upfront: 49%
- NPV of Royalty Payments: 44%

Getting Clearer?

Careful Using Comparables
How Much to Pay and Deal Structuring?

Cash Flow vs Risk

Fees / Milestones vs. Costs / Risk

Royalties vs. Op. Profits

Cash Flow vs Risk

Cash Flow ($USmillions)

Year (Launch = 0)

Probability of Downside

-50 -40 -30 -20 -10 0 10 20 30 40 50

-20% -10% 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Cash Flow Risk

Cash Flow

DILLON CAPITAL

S T R A T E G I E S

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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%
# Cash Flow Forecast Excerpts

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<td>8.9</td>
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<td>164.8</td>
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<td>(6.8)</td>
<td>(20.3)</td>
<td>(33.8)</td>
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<td><strong>Net Cash Flow - Partner</strong></td>
<td>(54.5)</td>
<td>(13.4)</td>
<td>(22.3)</td>
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<td>(35.6)</td>
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<td>Taxable Milestones Earned</td>
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<td>Other Expenses (Includes deal costs)</td>
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<td>Net EBITDA</td>
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<tr>
<td>PV</td>
<td>-</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Net Cash Flow - Originator</strong></td>
<td>50.0</td>
<td>-</td>
<td>-</td>
<td>6.6</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>26.4</td>
<td>9.8</td>
<td>28.2</td>
<td>43.2</td>
</tr>
<tr>
<td><strong>Product Total:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product EBITDA</td>
<td>(6.8)</td>
<td>(20.3)</td>
<td>(33.8)</td>
<td>(54.0)</td>
<td>(54.0)</td>
<td>(54.0)</td>
<td>(54.0)</td>
<td>(6.8)</td>
<td>168.6</td>
<td>459.3</td>
<td>653.3</td>
<td>707.3</td>
</tr>
<tr>
<td>Terminal Value</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PV</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Net Cash Flow - Total Product</strong></td>
<td>(4.5)</td>
<td>(13.4)</td>
<td>(22.3)</td>
<td>(35.6)</td>
<td>(35.6)</td>
<td>(35.6)</td>
<td>(35.6)</td>
<td>(4.5)</td>
<td>79.4</td>
<td>252.6</td>
<td>397.4</td>
<td>457.4</td>
</tr>
</tbody>
</table>

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

Cash Flow Share

<table>
<thead>
<tr>
<th>Year</th>
<th>Partner Cash Flow Share (US millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>-100</td>
</tr>
<tr>
<td>2006</td>
<td>0</td>
</tr>
<tr>
<td>2008</td>
<td>100</td>
</tr>
<tr>
<td>2010</td>
<td>200</td>
</tr>
<tr>
<td>2012</td>
<td>300</td>
</tr>
<tr>
<td>2014</td>
<td>400</td>
</tr>
<tr>
<td>2016</td>
<td>500</td>
</tr>
<tr>
<td>2018</td>
<td>600</td>
</tr>
<tr>
<td>2020</td>
<td>700</td>
</tr>
<tr>
<td>2022</td>
<td>800</td>
</tr>
<tr>
<td>2024</td>
<td>900</td>
</tr>
</tbody>
</table>

Fees / Milestones vs. Costs / Risk
Royalties vs. Op. Profits

Partners: Partner, Originator

DILLON CAPITAL STRATEGIES
Resulting Shares of the Pie

Total Net Present Value ($US millions)
Total Value = $1002

- $820 (82%)
- $182 (18%)

Legend:
- Blue: Originator
- Maroon: Partner
Investment and Milestone Risk Gaming

<table>
<thead>
<tr>
<th>Phase</th>
<th>PreClinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Registration</th>
<th>Launch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program's Probability of Launch</td>
<td>11%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Probability of Progressing</td>
<td>59%</td>
<td>52%</td>
<td>57%</td>
<td>70%</td>
<td>90%</td>
<td></td>
</tr>
<tr>
<td>Probability of Failure in Phase</td>
<td>41%</td>
<td>48%</td>
<td>43%</td>
<td>30%</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>Probability of Phase's Cashflow</td>
<td>100.0%</td>
<td>59.0%</td>
<td>30.7%</td>
<td>17.5%</td>
<td>12.2%</td>
<td></td>
</tr>
</tbody>
</table>

Probability of Phase's Cashflow:

- PreClinical: 100.0%
- Phase I: 59.0%
- Phase II: 30.7%
- Phase III: 17.5%
- Registration: 12.2%
- Launch: 0.0%

DILLONCAPITAL
STRATEGIES
Risk and Value Sharing

Cash Flow Share

($US millions)

Probability of Cash Flow

Partner  Originator  Probability of Cash Flow


0  0  0  0  0  0  0  0  0  0  0

-100  -200  -300  -400  -500  -600  -700  -800  -900  -1000

-20%  -40%  -60%  -80%  0%  20%  40%  60%  80%  100%
Adjusted Value Sharing

Probabilized and Discounted Cash Flow Share

($US millions)

Partner  Originator

DILLON CAPITAL
S T R A T E G I E S

119
Shares of the Pie – Simple Method

Total Net Present Value ($US millions)

Total Value = $1002

- $820 (82%)
- $182 (18%)

Legend:
- Originator
- Partner
Resulting Shares of the Pie – Phased Method

Risk-adjusted Net Present Value ($US millions)

Total Value = $91

- Originator: $61 (67%)
- Partner: $30 (33%)

Phased Method
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

Comparison of Phased and Simple Probability Adjusting
Share of Risk-adjusted Value

- Phased: 67% to 33%
- Simple: 82% to 18%

Legend:
- **Originator**
- **Partner**
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

$45.5
50%

$45.5
50%

Originator
Partner
Value Adding

Risk Adjusted Value

(PC P I P II P III Reg Launch
($USmillions)

0 500 1000 1500 2000 2500 3000

DILLON CAPITAL
S T R A T E G I E S

125
Partnering Timing - Shifting Value Shares

Risk Adjusted Share of Value

<table>
<thead>
<tr>
<th>PC</th>
<th>P I</th>
<th>P II</th>
<th>P III</th>
<th>Reg</th>
<th>Launch</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td></td>
<td></td>
<td>80%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20%</td>
<td></td>
<td></td>
<td>60%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40%</td>
<td></td>
<td></td>
<td>40%</td>
<td>80%</td>
<td></td>
</tr>
<tr>
<td>60%</td>
<td></td>
<td></td>
<td>20%</td>
<td>60%</td>
<td></td>
</tr>
<tr>
<td>80%</td>
<td></td>
<td></td>
<td>0%</td>
<td>40%</td>
<td></td>
</tr>
<tr>
<td>100%</td>
<td></td>
<td></td>
<td>20%</td>
<td>20%</td>
<td></td>
</tr>
</tbody>
</table>

Legend: □ Partner □ Originator
Pre-Partnering - Investment vs. Return

Development Cost vs Value ($USMM)

Risk Adjusted Value

Development Spend

PC P I P II P III Reg Launch

Risk Adjusted Value Development Spend
Pre-Partnering - Investment vs. Return

Development Cost vs Value ($USMM)

Risk Adjusted Value

Development Spend

PC P I P II

321 61

IIR = 99%
P(s)

11% 36%

Risk Adjusted Value Development Spend

DILLON CAPITAL STRATEGIES
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
  - 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

<table>
<thead>
<tr>
<th>Cost of future capital to be invested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upfront, milestones &amp; options</td>
</tr>
<tr>
<td>Milestones, options</td>
</tr>
<tr>
<td>Royalty rate &amp; “bonus” payments</td>
</tr>
<tr>
<td>Term, royalty tier, option</td>
</tr>
<tr>
<td>Definitions, limits, sharing</td>
</tr>
<tr>
<td>Definitions, limits, bonus payments</td>
</tr>
<tr>
<td>M&amp;A, equity stake, loans</td>
</tr>
<tr>
<td>R&amp;D subsidies, staff sharing</td>
</tr>
<tr>
<td>Profit share, S&amp;M share, splits</td>
</tr>
</tbody>
</table>
Thank You

Joe Dillon
President

Bringing money to medicine®

202.255.3780
jdillon@dilloncapital.com