



Business Development Basics Course

Finance Concepts in Licensing

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FINANCE CONCEPTS IN LICENSING

Valuation Methodology

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Building a Business Development Model

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Why is valuation in life sciences so complex?

Hi-tech



9
months



Beta
launch
(90%+ POS)

Biotech



12-15
years



Product
approval
(5% POS)



Financial Objectives of Licensing

- To add to or protect the value of the company
- To determine what is the value of a product, technology or program to be licensed
- To determine how this value is measured

We need a valuation methodology



“Win-Win” is the Key Objective for Licensing

Deals need to be done on a rational basis

- **Entrepreneurs** and **investors** need to be incented to put time and money at risk
- **Pharma** needs to be incented to license products, make money and license more products

We all want to get the deal done



Today's Objective: Develop a Valuation Methodology

Continually and consistently applied **Management Tool**

Key benefits

- Improves the quality of decisions
- Enables better deal terms



Highly desirable features

- High utility
- Understandable
- Easy to administer and maintain



High Utility of Valuation Methodology

- Supporting transactions
- Facilitating internal management decisions
- Supporting external pricing (e.g., stock price)



Today's Objective: Develop a Valuation Methodology

Acceptance of results depends on agreement with the method

- Management
- Board of Directors
- Employees
- Prospective licensing party
- Corporate partners
- Investors
- Wall Street analysts

Need to align key stakeholders



Valuation Method Should Be Easy to Administer

- **Should be consistently applied to all programs**
- **Should be regularly updated and maintained**
 - New information
 - New estimations supported by reason
 - Current financial market data
- **Bias-free**
 - Input from Finance, Bus Dev, Marketing, Research, Clinical



Valuation Methodologies

1. Sunk Cost
2. Sum of Parts
3. Comparables
4. Discounted Cash Flow (DCF)
5. Risk-adjusted NPV (rNPV)
6. Real Options Analysis



Sunk Costs

- Using paid-in capital to date as a valuation method
- Typical approach says “We’ll give you a 5x return” but in some cases, may not even offer you 100% of paid-in

Strengths

- Verifiable (mostly)
- In some cases, guaranteed multiple

Weaknesses

- No one will pay for wasted money and may disagree with how money was spent
- Capped upside
- If someone offers you this, it’s because they think your asset is worth a lot more



Sum of Parts

- **Situation: Lead product failed and business is being liquidated**
- **Approach asks “What is the value of each asset?”**
(Real estate owned/leases, IP, equipment, employment contracts, distribution agreements, existing sales force)

Strengths

- Best used with a business that has substantial assets to liquidate (i.e., fire sale)

Weaknesses

- Typically receives pennies on the dollar
- Not applicable to ongoing business



Comparables – Product Valuation

- Derives sales and costs based on comparable products
- Example: For an oncology product (cytotoxic), compare sales for existing cytotoxics, including average peak sales

Strengths

- Can get actual sales data
- Minimal modeling; just use averages for line inputs

Weaknesses

- Power of the valuation is limited by how good the comp is
 - Is the product profile similar?
 - Is the environment when you launch in 4 years going to be the same?
 - Payers, competitors, generics



Comparables – Deal Valuation

Key question is what would a partner/acquirer pay based on “similar” deals?

Strengths

- Can get actual deal data, can get it for specific partners (terms, structure, trends)
- Minimal modeling; just target deals similar to your asset

Weaknesses

- Bias toward large deals: most deals don't rise to material level for the large partner, or aren't good enough so that the small partner wants to brag
- Most deals don't show terms; of those that do:
 - Situations are different
 - Underlying products are different
 - Most terms are redacted or combined into “biobucks”



Discounted Cash Flow/Risk-Adjusted NPV

- **Approach: Both use cash flow as their key metric**
 - Cash flow is change in cash balance in a specified period of time
 - For any program past launch: **CASH FLOW = Sales (cash generated) – (COGS – SG&A – taxes) (cash used)**
 - Prior to launch, cash flow is a negative value unless out-license
 - Time period of cash flow must be identified
- **Key concept: Time Value of Money**
 - Money now is worth more than money later
 - Cash received later in time is “discounted” by the interest you could have received had you that cash to invest now



Key Difference Between DCF and rNPV

DCF uses discount rate to account for both development risk and cost of capital (e.g., 25% or 30% rate for early stage products)

rNPV uses stage probabilities of success for each stage of development, along with a cost of capital discount factor

Effectively multiplies cash flows by the probability of their occurrence



Why Might rNPV Be a Superior Methodology in Licensing Over DCF?

- Distinguishes risky, novel programs from less risky reformulation programs by using stage probabilities
- Allows determination of explicit risk to next milestone; don't see step up in value when get to the next phase



Real Options Analysis

- **Similar to rNPV, but allows you to account for changes in conditions such that you can account for new decisions in the future**
- **Example: you assume \$400M peak sales and estimate \$80M of fixed sales and marketing costs to support those sales**
 - Six years out, actual sales are only \$70M; you would adjust those costs down or terminate the asset



Results of Valuation Survey

Multiple approaches:

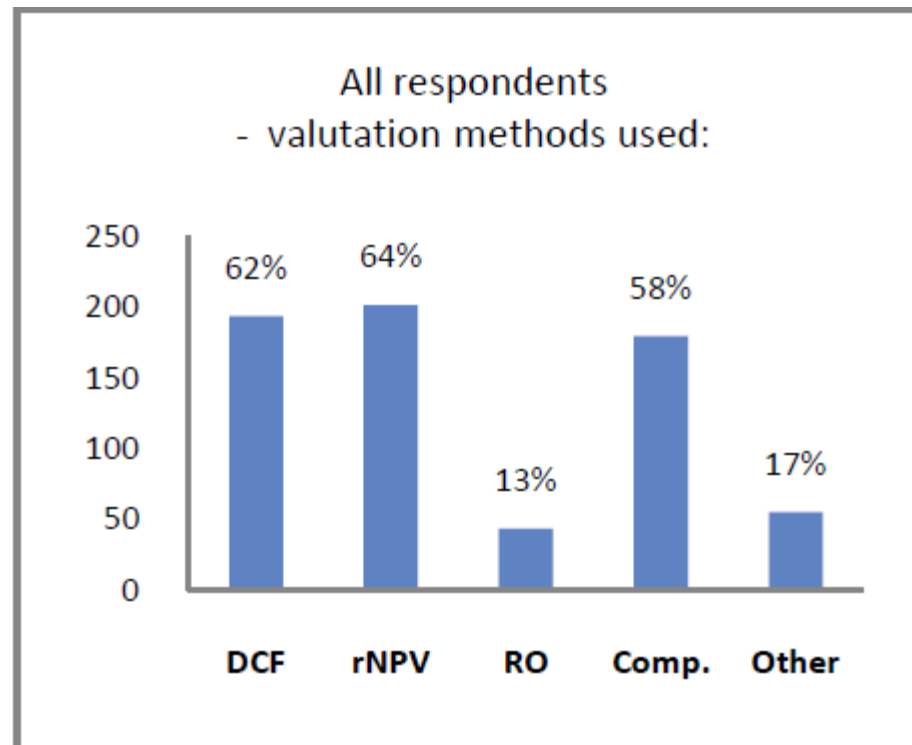
- Sunk cost
- Sum of parts
- Comparables
- Discounted Cash Flow (DCF)
- Risk-adjusted NPV (rNPV)
- Real options analysis

Which of these valuation methodologies are used most often in life sciences analytics?



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Used Most Often Across Areas



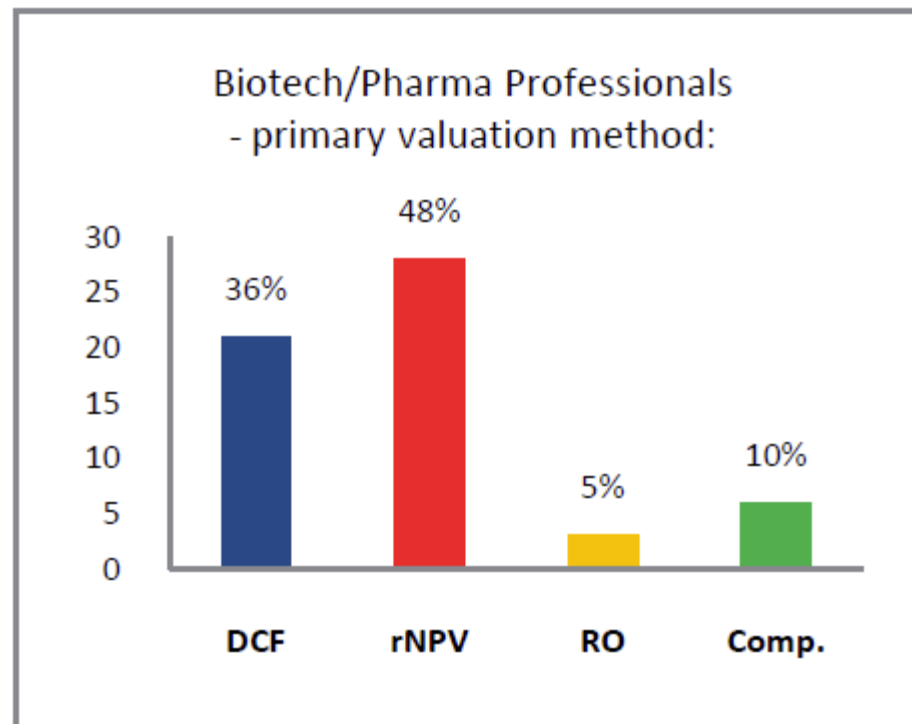


Which Methods Do Pharmas Use Most?



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Used Most Often by Biotechs/Pharmas



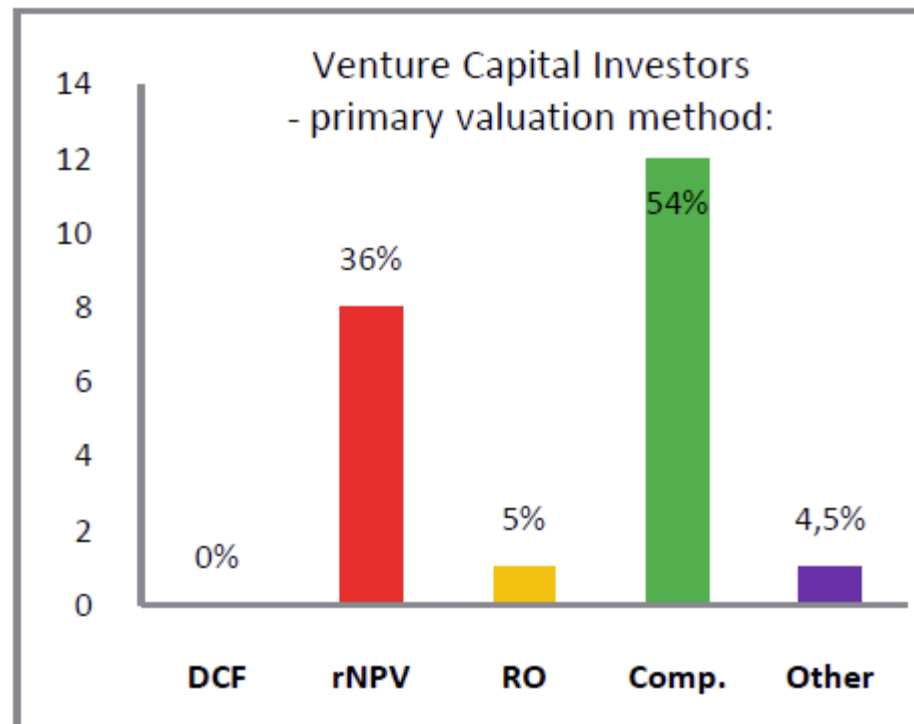


Which Methods Do VCs Use Most?



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Used Most Often by VCs





Cash Flow is the Best Metric

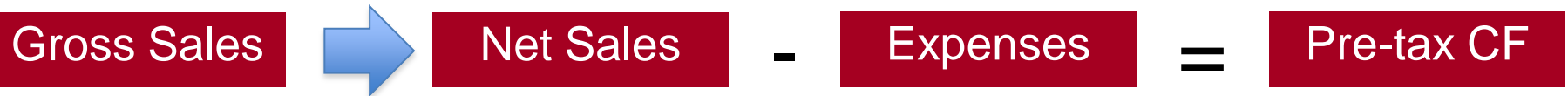
- Change in cash balance in a specified period of time
- Most easily verifiable compared to an accounting term such as “net income”
- Cash is king





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Driving to Cash Flow and NPV



Less rebates, returns,
discounts, samples

Dev Costs
Manufacturing Costs
Marketing and Sales Costs
Outgoing License Costs



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Product X WW Product P&L

All Indications Base Case Given Success (pretax)

WW Product P&L - All Indications and Territories (\$ mm)

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Gross Sales																	
SLE	\$ -	\$ -	\$ -	\$ -	\$ 27	\$ 238	\$ 508	\$ 786	\$ 1,046	\$ 1,274	\$ 1,340	\$ 1,305	\$ 1,268	\$ 1,263	\$ 1,280	\$ 1,174	\$ 781
RA	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 55	\$ 183	\$ 338	\$ 497	\$ 659	\$ 789	\$ 837	\$ 847	\$ 857	\$ 763	\$ 489
MS	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 82	\$ 266	\$ 483	\$ 706	\$ 935	\$ 1,114	\$ 1,177	\$ 1,192	\$ 1,207	\$ 1,075	\$ 689
GvHD	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 11	\$ 37	\$ 68	\$ 100	\$ 133	\$ 159	\$ 169	\$ 171	\$ 173	\$ 154	\$ 99
Total Gross Sales	\$ -	\$ -	\$ -	\$ -	\$ 27	\$ 238	\$ 656	\$ 1,271	\$ 1,936	\$ 2,577	\$ 3,067	\$ 3,368	\$ 3,451	\$ 3,473	\$ 3,517	\$ 3,166	\$ 2,058
Discounts and Rebates	\$ -	\$ -	\$ -	\$ -	\$ 3	\$ 29	\$ 79	\$ 153	\$ 232	\$ 309	\$ 368	\$ 404	\$ 414	\$ 417	\$ 422	\$ 380	\$ 247
Total Net Sales	\$ -	\$ -	\$ -	\$ -	\$ 24	\$ 209	\$ 577	\$ 1,119	\$ 1,703	\$ 2,268	\$ 2,699	\$ 2,964	\$ 3,037	\$ 3,056	\$ 3,095	\$ 2,786	\$ 1,811
Expenses																	
Development Costs	\$ 64	\$ 88	\$ 145	\$ 109	\$ 100	\$ 25	\$ 11	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Costs of Goods Sold	\$ -	\$ -	\$ -	\$ -	\$ 2	\$ 19	\$ 50	\$ 94	\$ 141	\$ 186	\$ 221	\$ 242	\$ 248	\$ 249	\$ 252	\$ 227	\$ 148
Sales and Marketing	\$ -	\$ -	\$ -	\$ 11	\$ 103	\$ 237	\$ 327	\$ 290	\$ 223	\$ 228	\$ 223	\$ 243	\$ 245	\$ 246	\$ 248	\$ 132	\$ 11
Outgoing Milestones	\$ 4	\$ -	\$ -	\$ 6	\$ 9	\$ 8	\$ 6	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Outgoing Royalties	\$ -	\$ -	\$ -	\$ -	\$ 2	\$ 23	\$ 70	\$ 148	\$ 236	\$ 320	\$ 385	\$ 425	\$ 436	\$ 438	\$ 444	\$ 316	\$ -
Total Expenses	\$ 68	\$ 88	\$ 145	\$ 127	\$ 217	\$ 311	\$ 464	\$ 532	\$ 600	\$ 734	\$ 829	\$ 909	\$ 929	\$ 934	\$ 944	\$ 674	\$ 159
Pre-tax Cash Flow	\$ (68)	\$ (88)	\$ (145)	\$ (127)	\$ (193)	\$ (102)	\$ 113	\$ 587	\$ 1,104	\$ 1,534	\$ 1,870	\$ 2,054	\$ 2,108	\$ 2,122	\$ 2,150	\$ 2,111	\$ 1,652



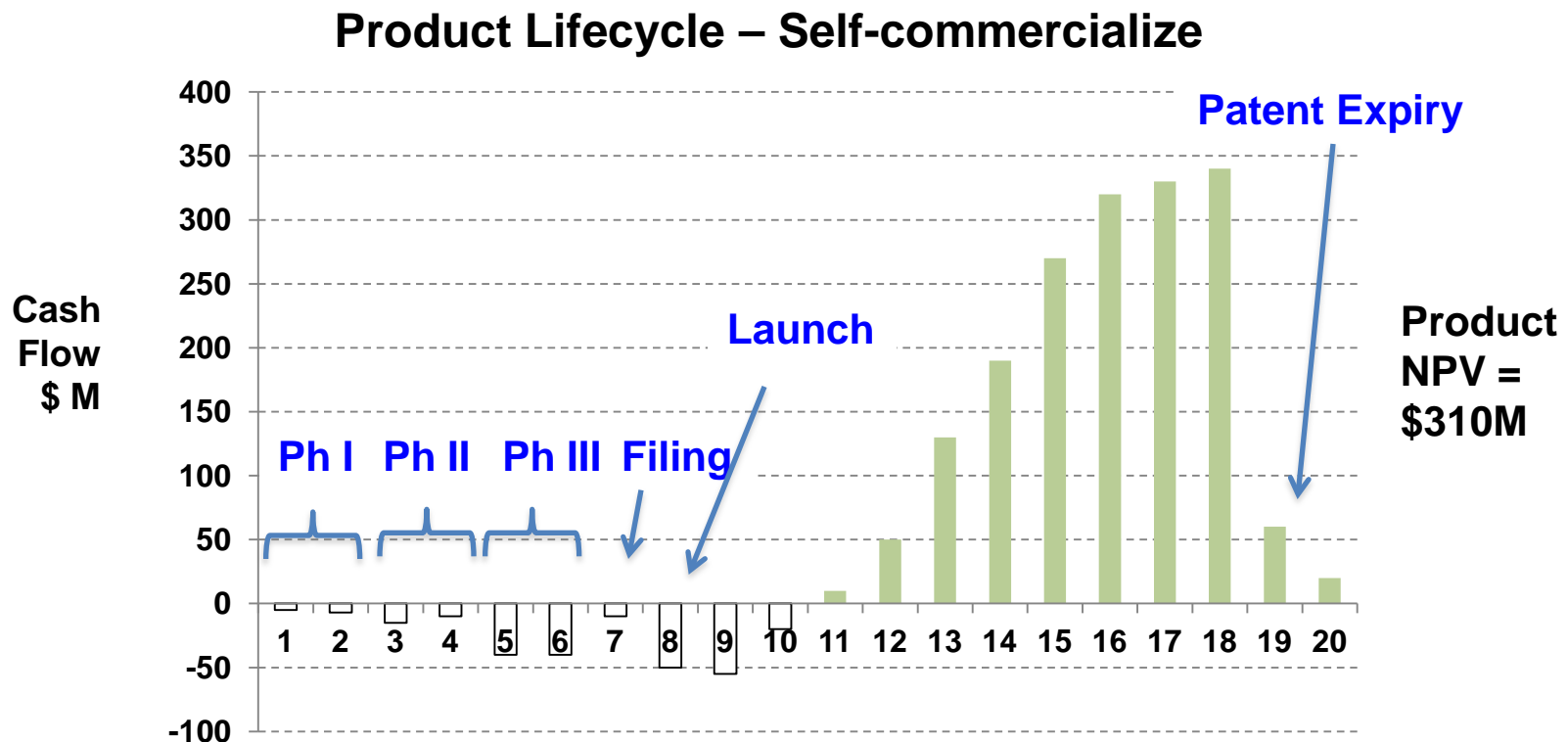
Valuation Should Account for Strategic Fit

- Since fit is strategic for licensee, several factors can enhance the cash flow
 - Fits licensee's clinical experience and relationships
 - Top quality investigators and advisors, optimal trial design
 - Quicker patient recruitment
 - May shorten overall length of trial
 - Preparation of NDA and probability of approval
 - Fits product portfolio and leverages marketing capabilities
 - Complements existing product, increases sales
 - Use existing sales force

Pie and therefore deal terms should increase with the right strategic partner

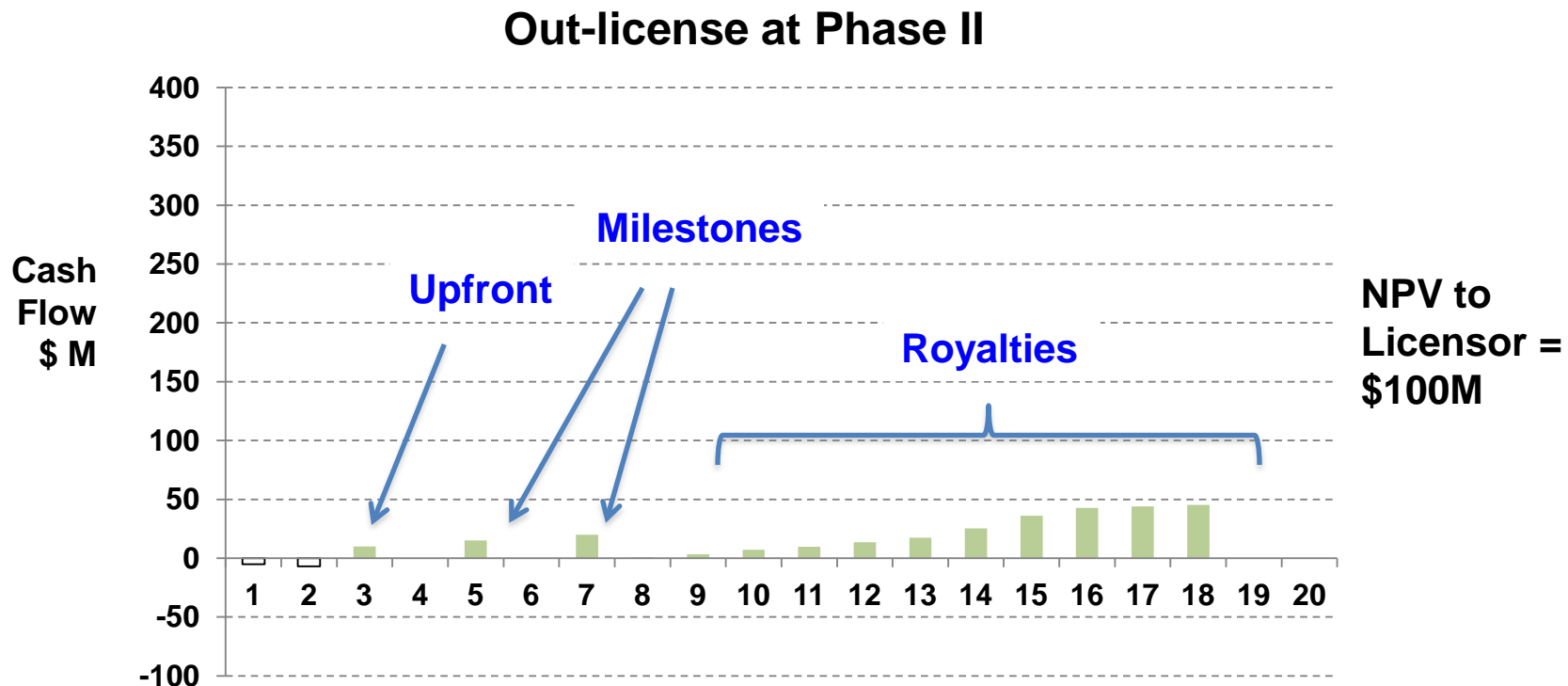


Program Cash Flow Example: Product Lifecycle



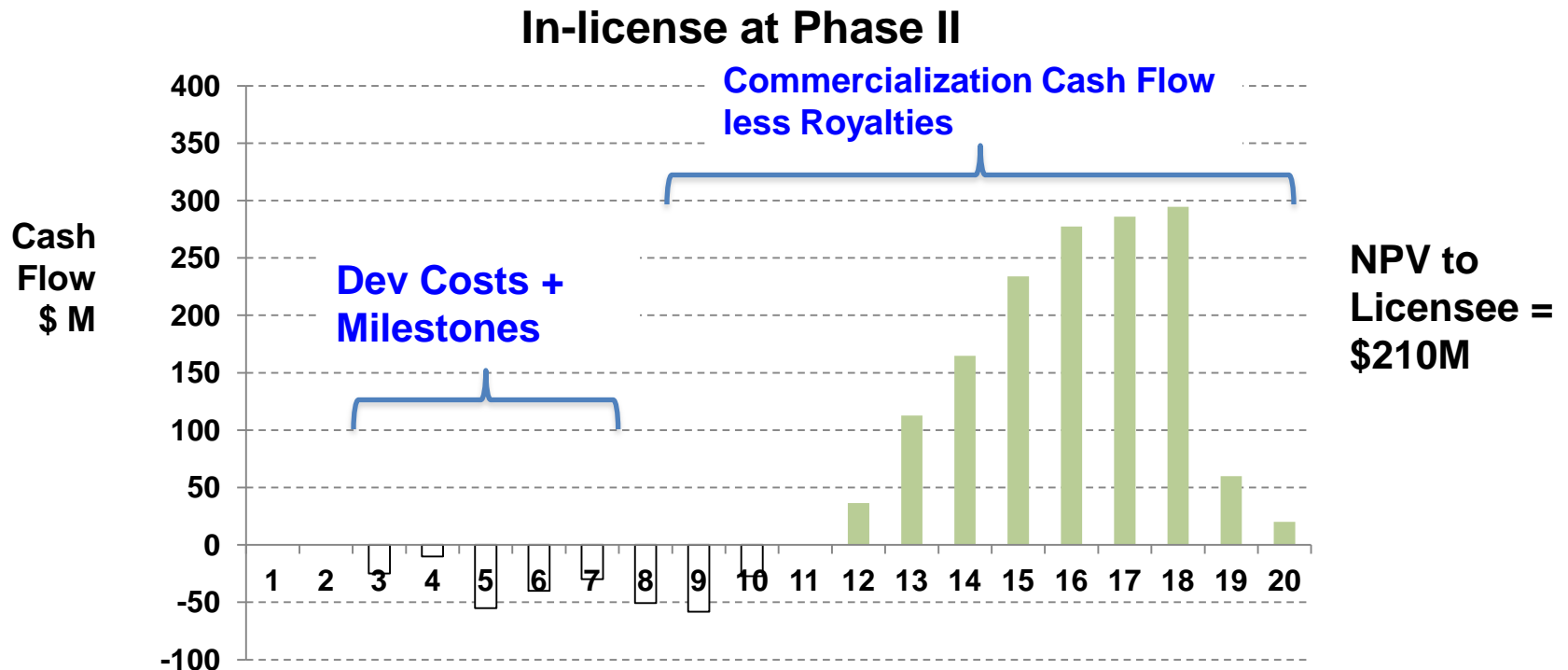


Program Cash Flow Examples: Out-Licensed Product





Program Cash Flow Examples: In-Licensed Product



A company's value in life sciences is determined in large part by these expected cash flows and by the degree of strategic combination and integration of its current and future programs

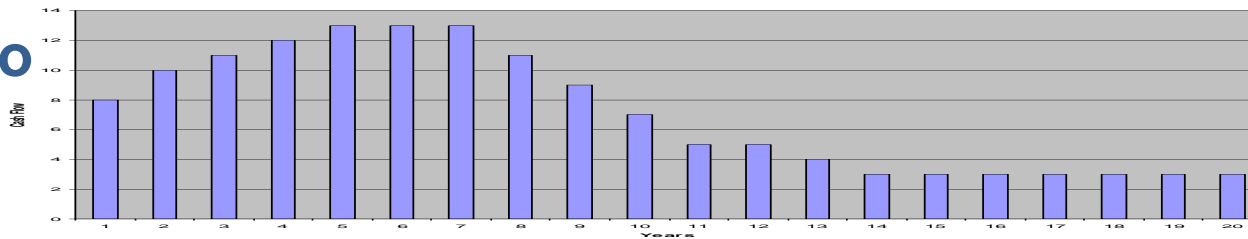




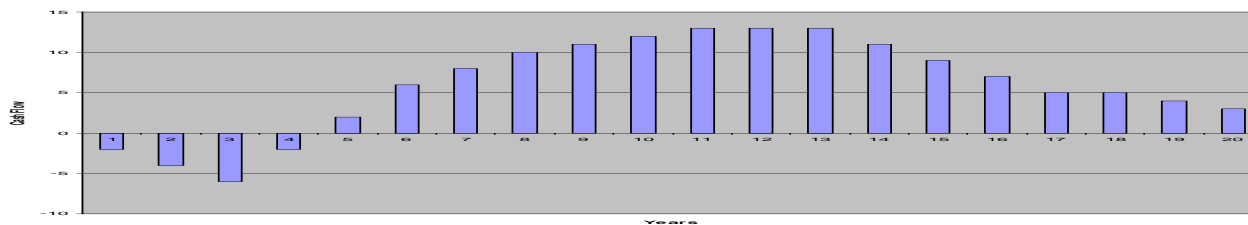
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Program Portfolio

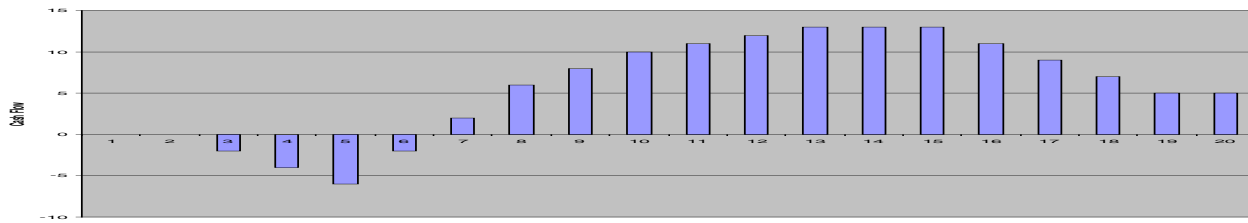
1. Commercial stage



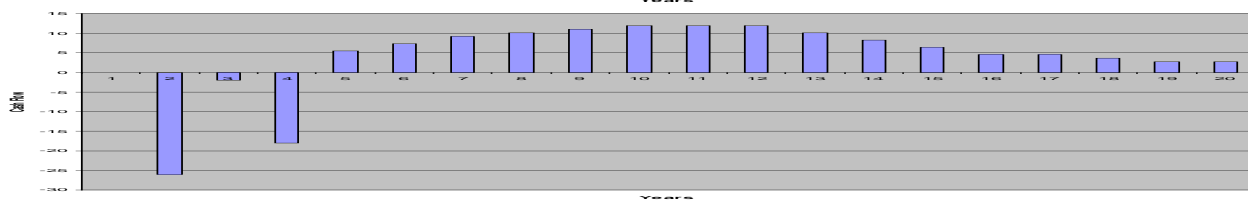
2. New product Yr 1



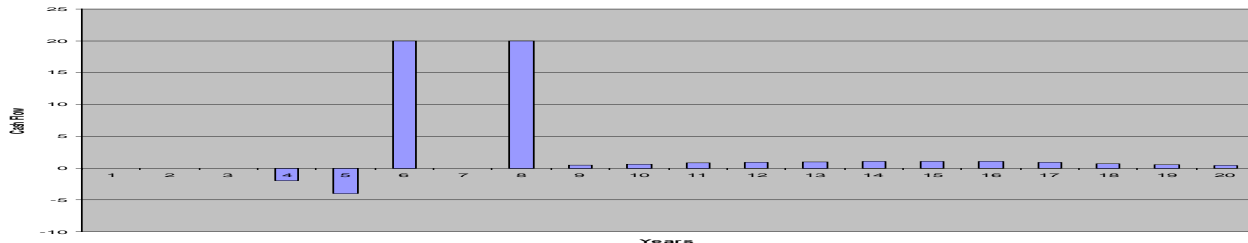
3. New product Yr 3



4. In-license Yr 2



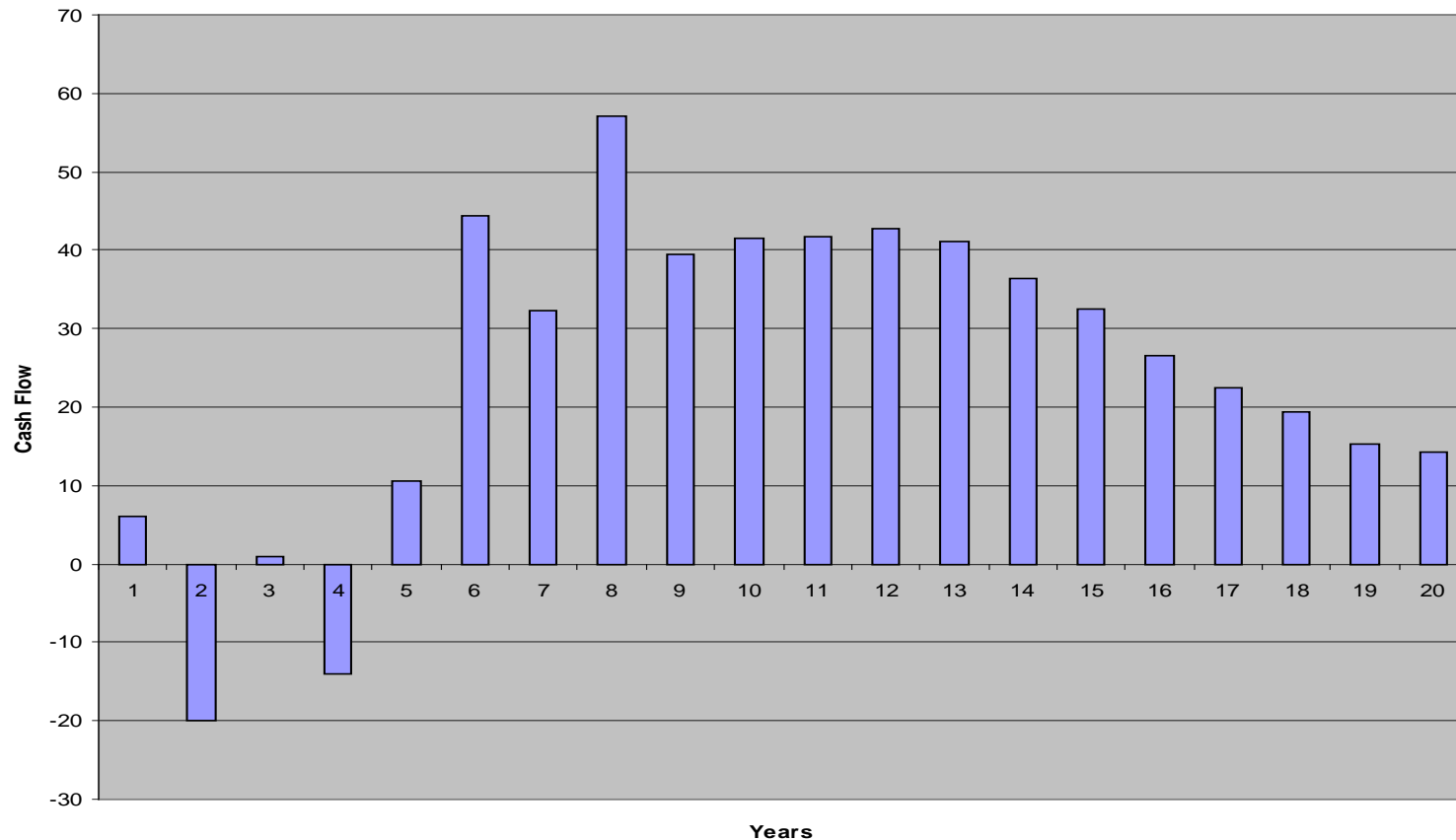
5. Out-license, begin Yr 4





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Company Cash Flow = Sum of Program
Cash Flows

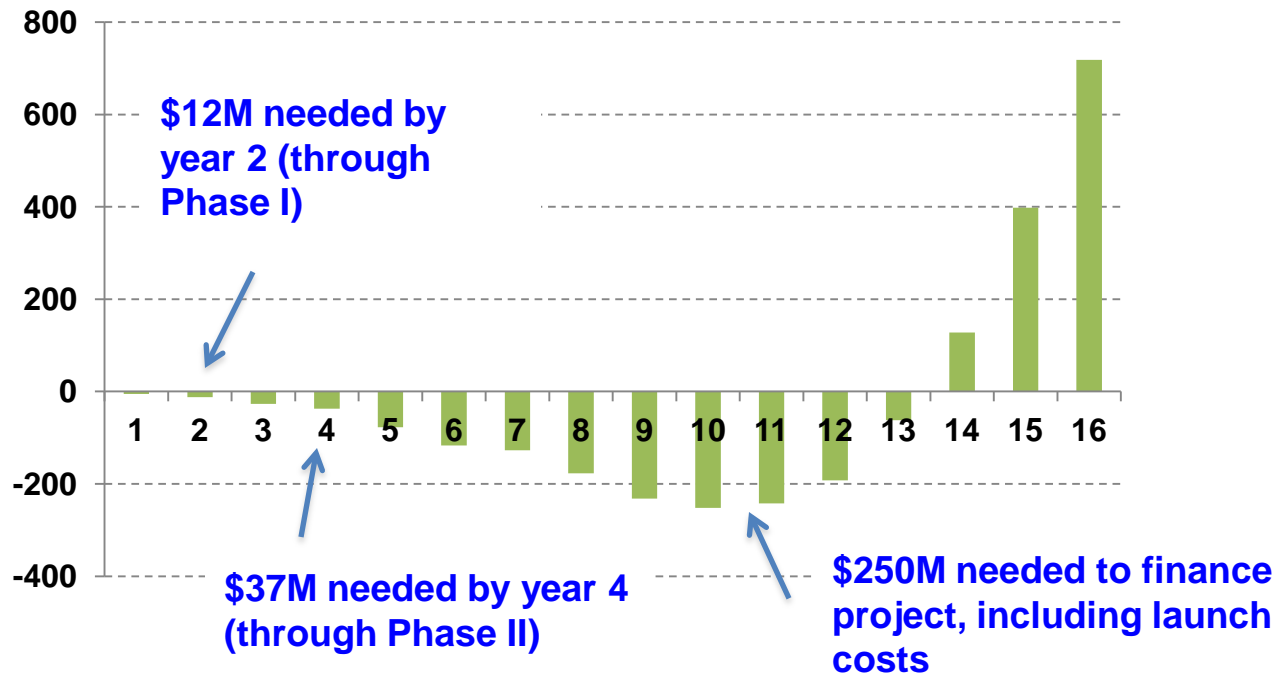




Cumulative Cash Flows = Cash Balances

Identifies Amount and Timing of Needed External Financing

**Cumulative Cash Flow –
Self-commercialization**





Summary: Valuation Enhances Decision Making, Capital Raising, and Licensing

- **Aligning expectations**
 - Well-analyzed potential returns and timing
- **Clarity of purpose**
 - Why? For which programs?
 - How much is needed? When?
- **Greater specificity / detail**
 - Determine proper level of depth of analysis
- **Confidence / credibility**
 - But: analysis is only as good as its weakest part

Clarity equals value



Valuation Methodology: Three Fundamental Concepts

1. **Expected value**
2. **Cost of capital**
3. **Present value**

- These are distinct concepts
- Each is measured or determined independent of the other two
- Requires methodical application of the three concepts in combination to calculate the value of the program



Expected Value

- **Weighted average of all possible values**
- **Independent of time**
- **Independent of cost of capital or discount rate**
- **Outcomes of events change expected value**

$$E[X] = x_1p_1 + x_2p_2 + x_3p_3 + \dots + x_np_n$$

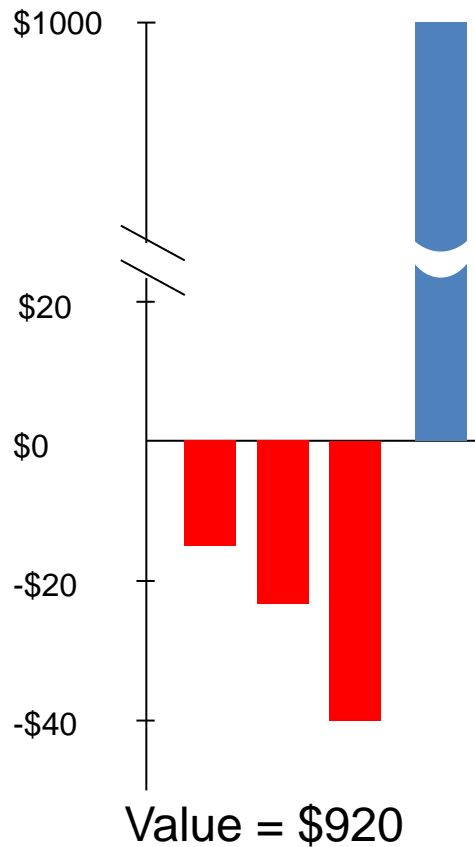
Where $p_1 + p_2 + p_3 + \dots + p_n = 1$



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Events 1, 2 and 3 must be performed in that order. Cost to perform Event 1 is \$15, cost for E2 is \$25, cost for E3 is \$40. If an event results in failure, then cannot proceed to next event. Success of E3 (and E1 and E2) is payout of \$1000.

Result A

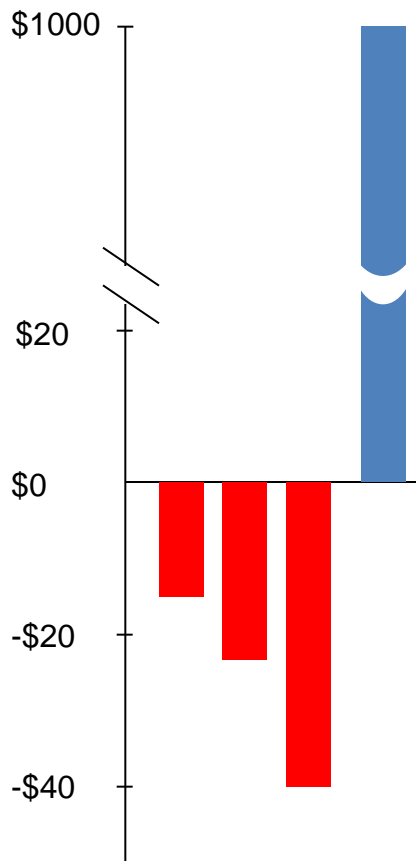




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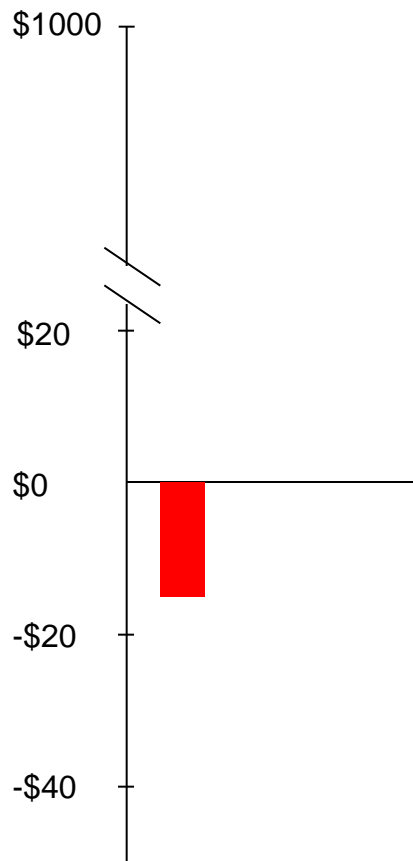
Four possible results, all under the exact same assumptions.

Result A



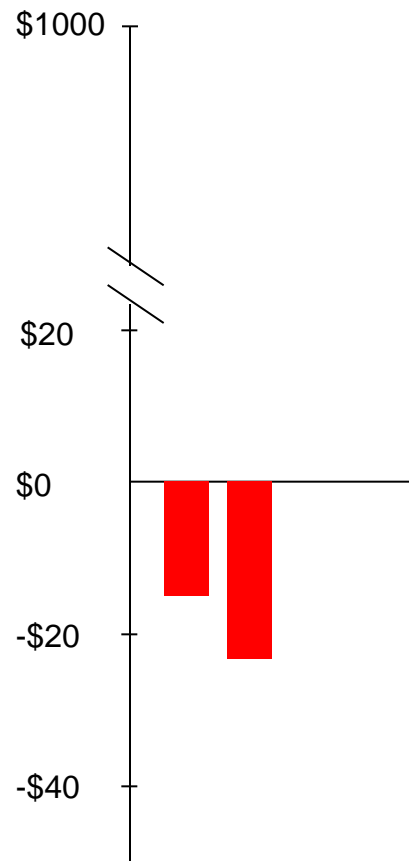
Value = \$920

Result B



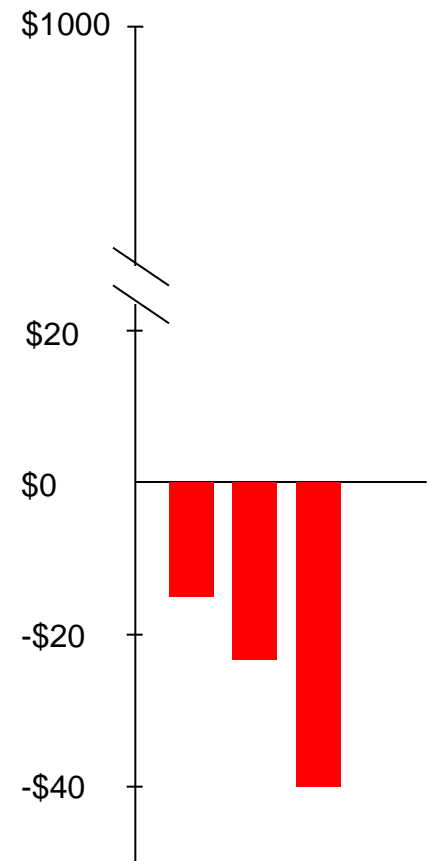
Value = -\$15

Result C



Value = -\$40

Result D



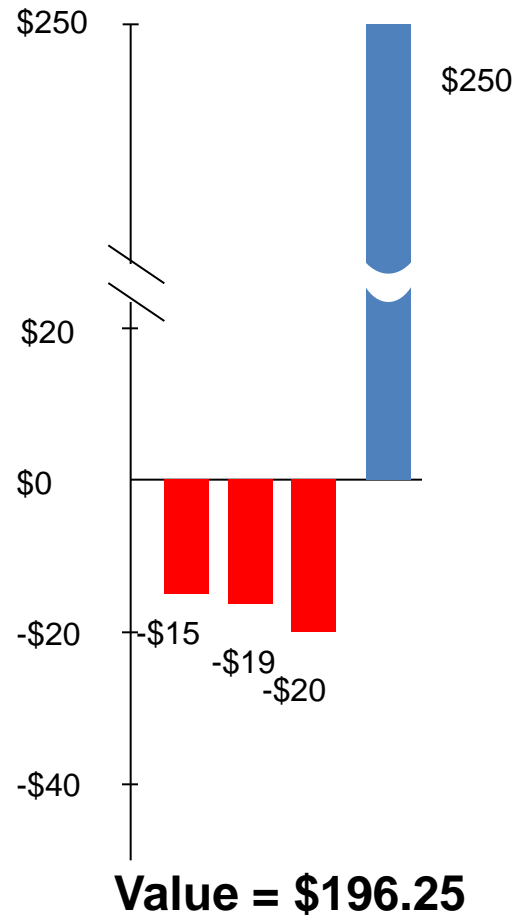
Value = -\$80



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Average the results?

Averages of Results



Perhaps the results should be weighted to calculate a weighted average result?



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$$\text{Value} = A \cdot p_a + B \cdot p_b + C \cdot p_c + D \cdot p_d$$

Which is the formula for Expected Value

$$E[X] = x_1p_1 + x_2p_2 + x_3p_3 + \dots + x_np_n$$

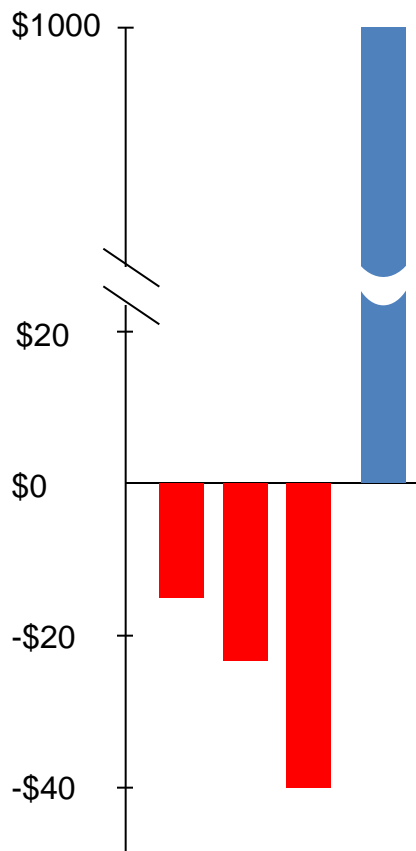
Where $p_1 + p_2 + p_3 + \dots + p_n = 1$

Need to know or assume the
probability of each possible result



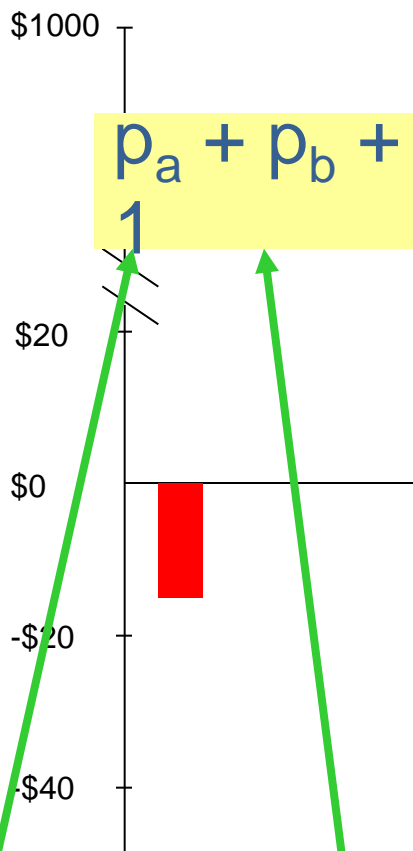
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Result A



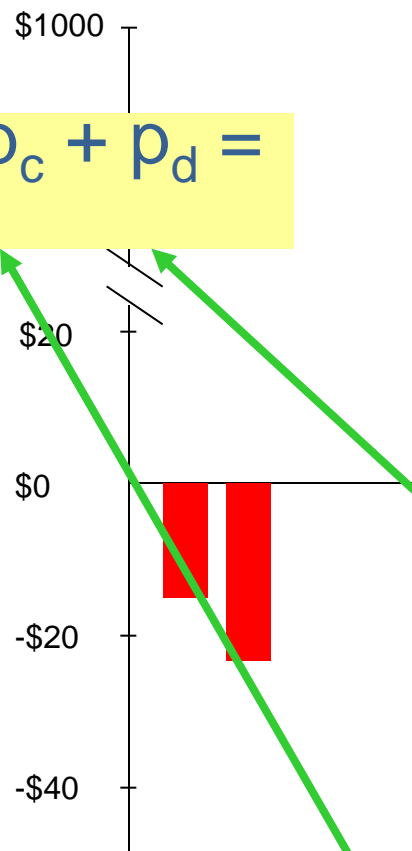
Value = \$920
Prob. = $.5 \times .5 \times .5 = .125$
Wgt Value = \$115

Result B



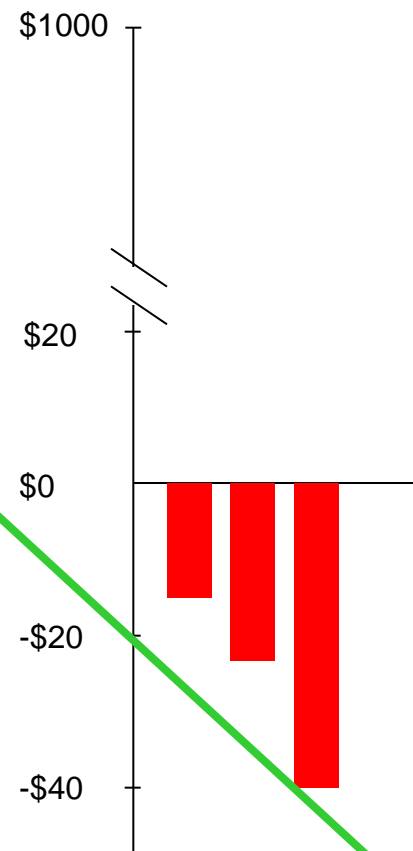
Value = -\$15
Prob. = .500
Wgt Value = -\$7.5

Result C



Value = -\$40
Prob. = $.5 \times .5 = .250$
Wgt Value = -\$10

Result D



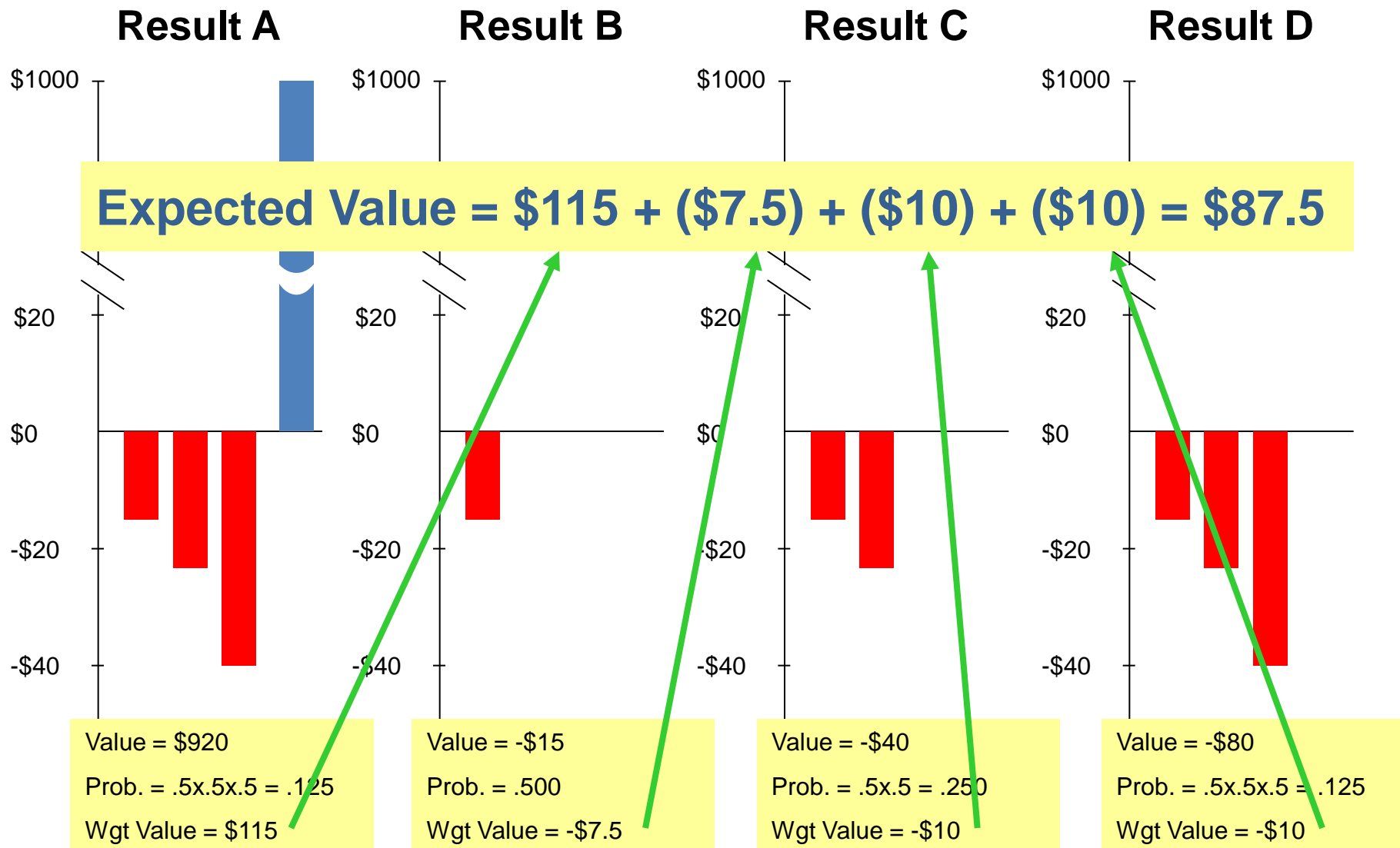
Value = -\$80
Prob. = $.5 \times .5 \times .5 = .125$
Wgt Value = -\$10

$$p_a + p_b + p_c + p_d =$$

1

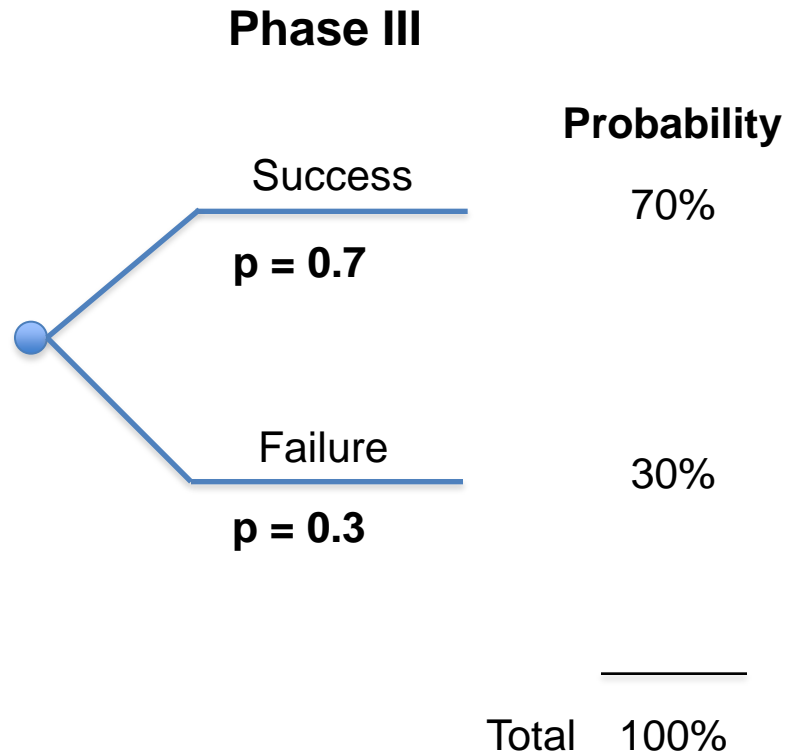


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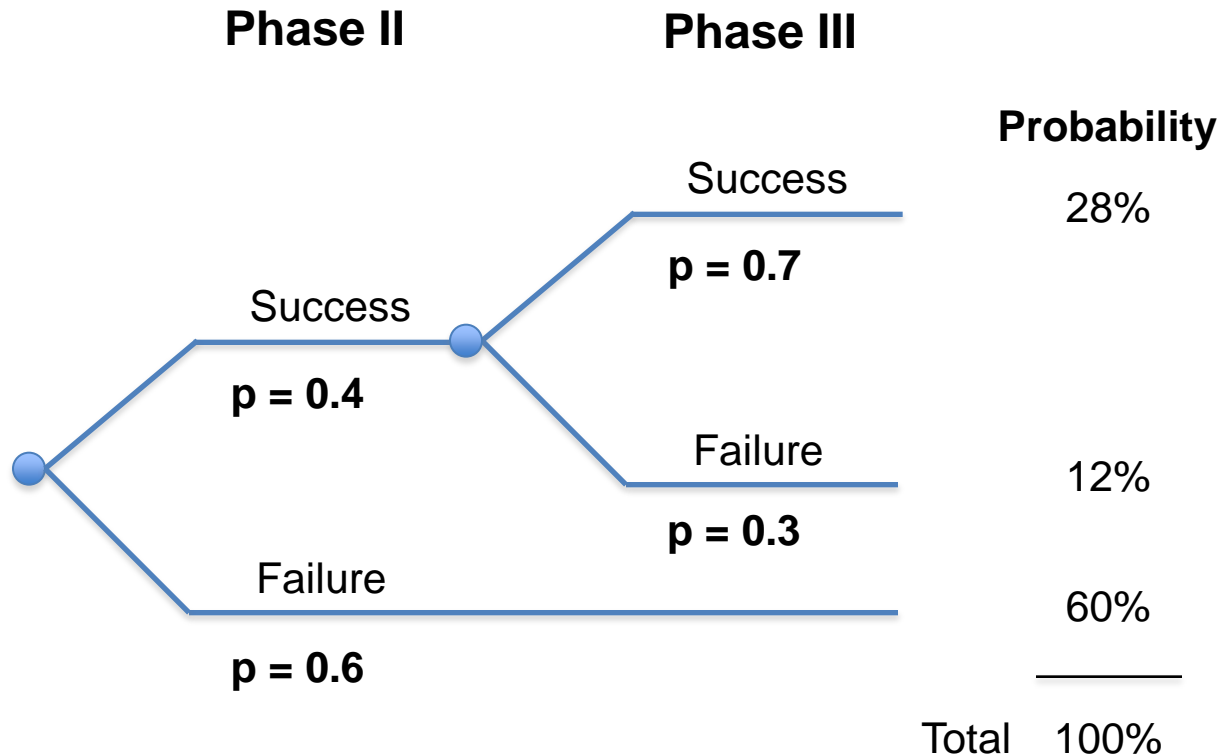


Additional Example: Decision Tree



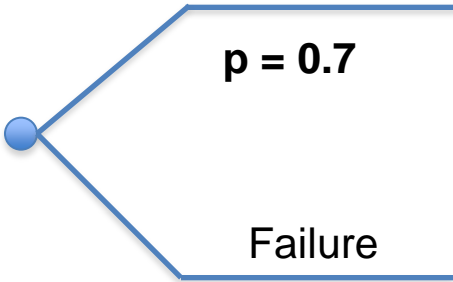


Additional Example: Decision Tree





Additional Example: Decision Tree

Phase III (cost \$40M)		Probability	Product Value Going Forward less Spent Cost	EV
	Success $p = 0.7$	70%	\$500M - \$40M = \$460M	320 (460×0.7)
	Failure	30%	$\$0 - \$40M$ $= -\$40M$	-12 (-40×0.3)

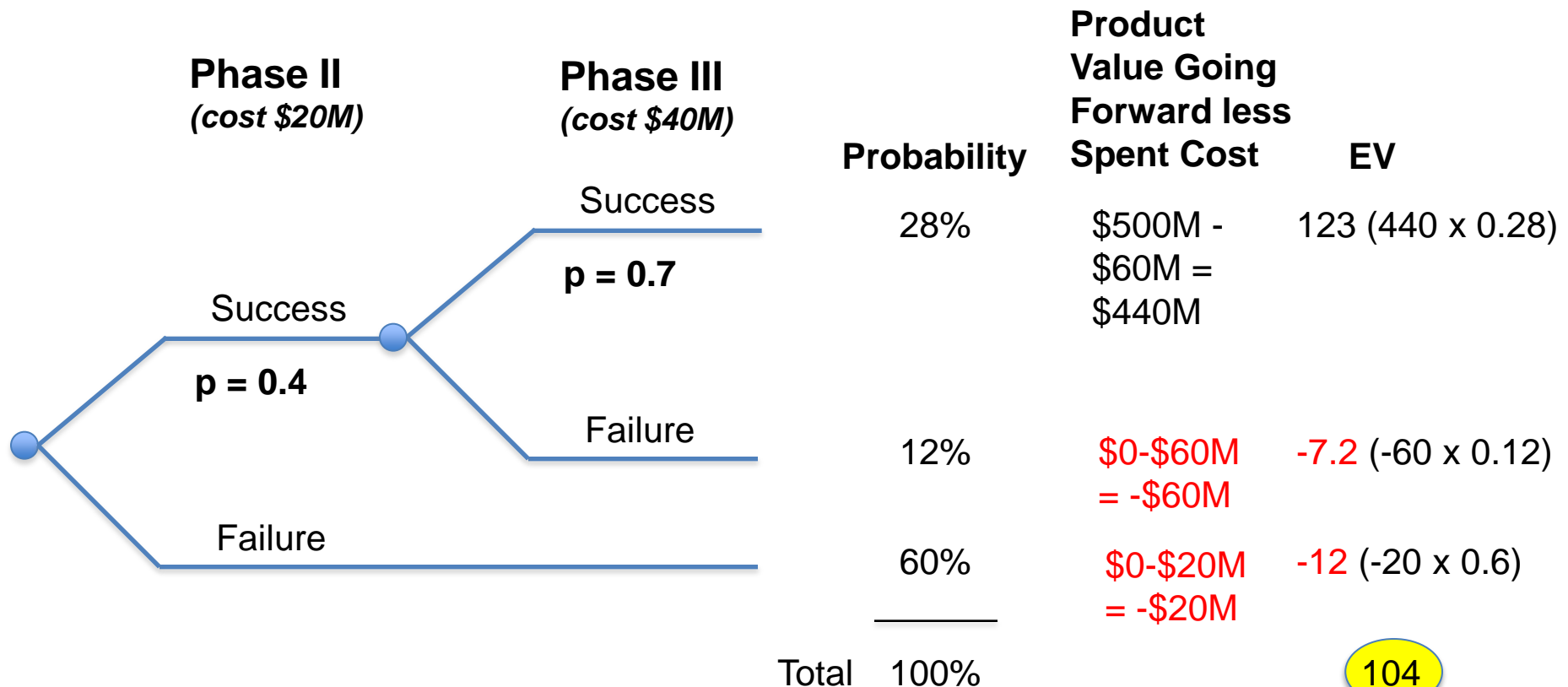
Given:

- \$40M cost of Ph III
- \$500M forward rNPV upon successful Ph III



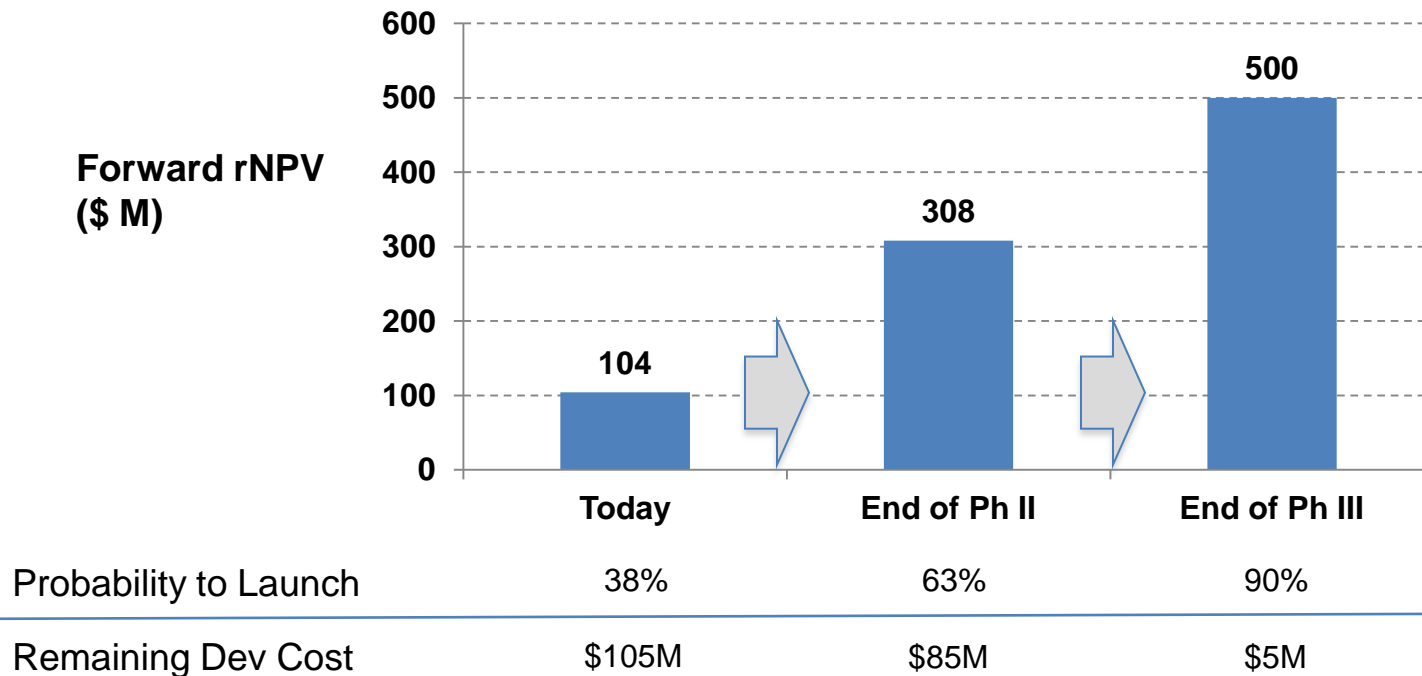
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Additional Example: Decision Tree





Step-up in Value Concept





Product value increases as you:

- **Resolve risk**
- **Have less remaining development cost**



What other factor haven't we discussed?



Time Value of Money!

- Key concept: \$1 received today is worth more than \$1 received in 5 years
- Why? Because you can invest that \$1 received today and get a return
- This concept is applied in valuation as a cost of capital (discount rate)



How to Determine Cost of Capital?

- Minimum investors want for a project of equal risk – “*hurdle rate*”
- It depends on how funds are used, not their source
- Concept of “opportunity cost”: it’s the cost of debt and equity to compensate creditors and shareholders
- Changes with changes in investors’ views of market, of the industry and of the company



Determination of Cost of Capital

- **Sole proprietor**
 - Sole discretion: “I don’t waste my time and money on any project that doesn’t promise at least a 10% return”
- **Venture capitalists**
 - Their institutional investors provide funds *to them* seeking 20+% returns
 - VC requires 25+% returns on prospective investments (basically a 5x return over 7 years)
- **Capital markets**
 - Primarily public markets for stocks and bonds
 - Institutional debt placement

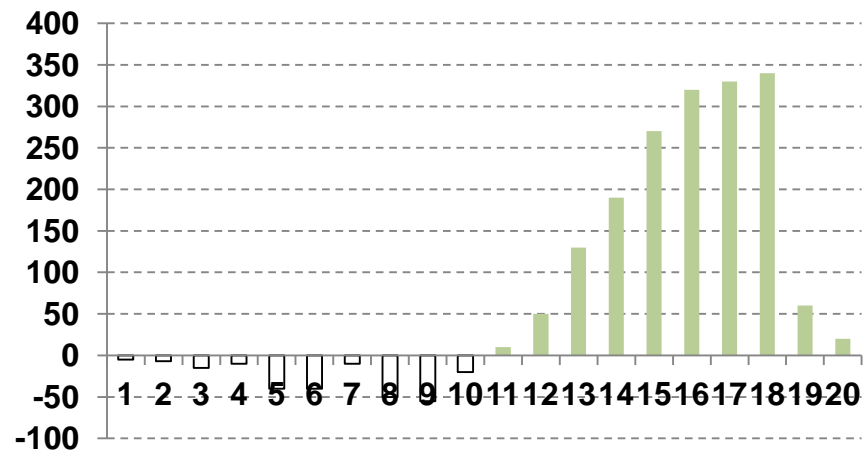


Discount Rate Has Major and Inverse Effect on Valuation

What rate should be used?

Discount Rate	NPV (\$M)
3.00%	\$930
10.00%	\$310
24.50%	\$0
30.00%	(\$25)

Product Lifecycle – Self-commercialize



Internal Rate of Return (IRR)

Discount rate that produces a break-even NPV. At rates less than IRR, the NPV is positive and the program is financially favorable. At rates greater than IRR, program is unfavorable.



Present Value

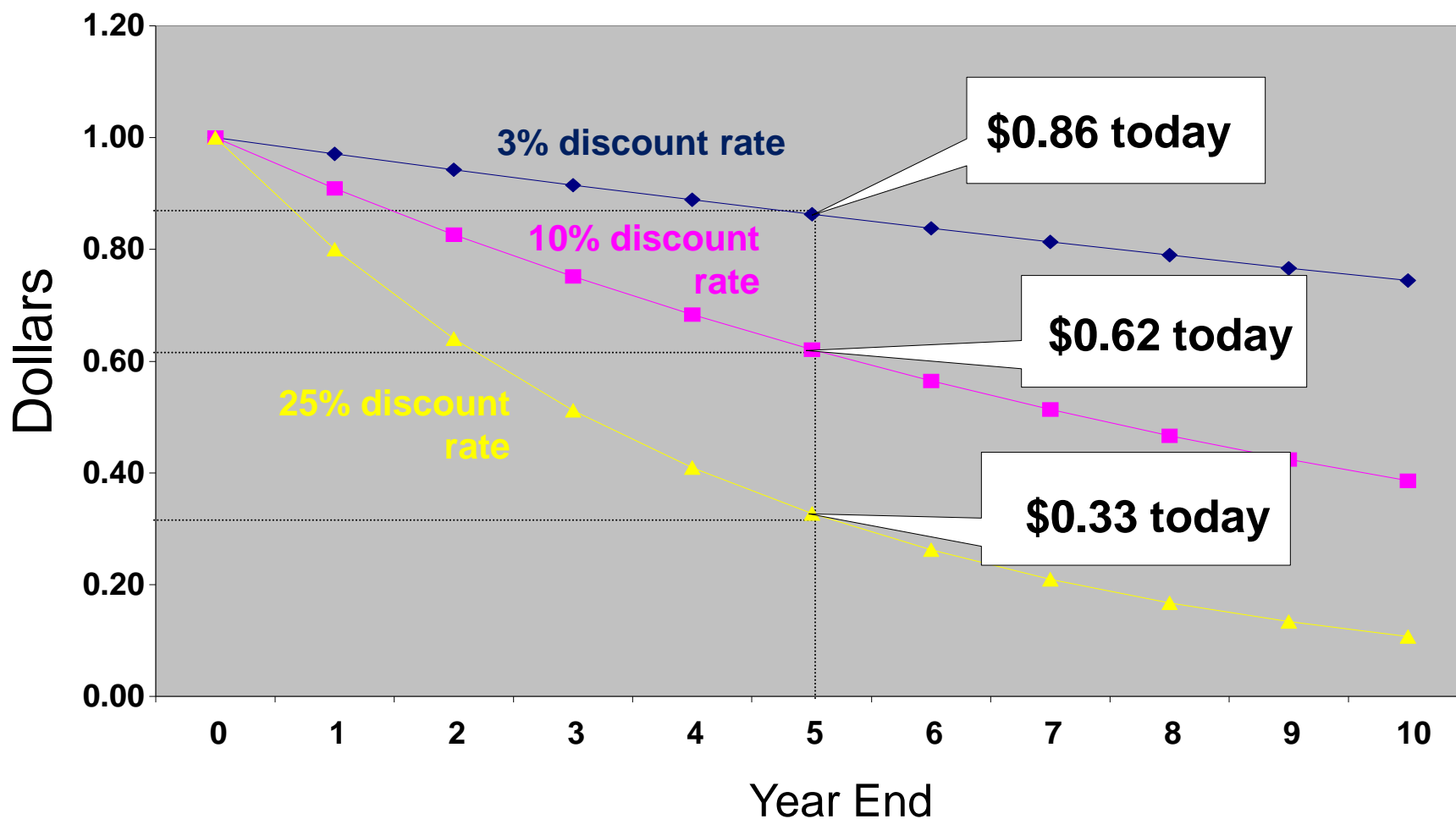
- Value at a given time of a single or series of payments or receipts at other times
- Dependent on time by definition
- Dependent on a discount rate

$$NPV = \sum_{t=0}^n \frac{CF_t}{(1+R)^t}$$



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Present Value Today of \$1 Received in 5 Years





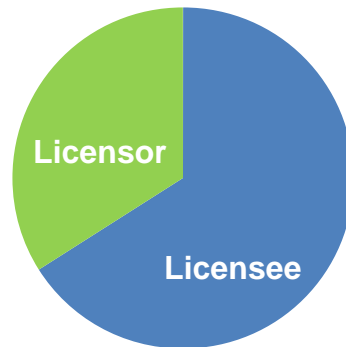
Discount Rate and Present Value

- As discount rate increases, value today of money received the future decreases.
- So higher discount rates mean lower asset value and lower deal terms.



So How Does This All Tie to Licensing?

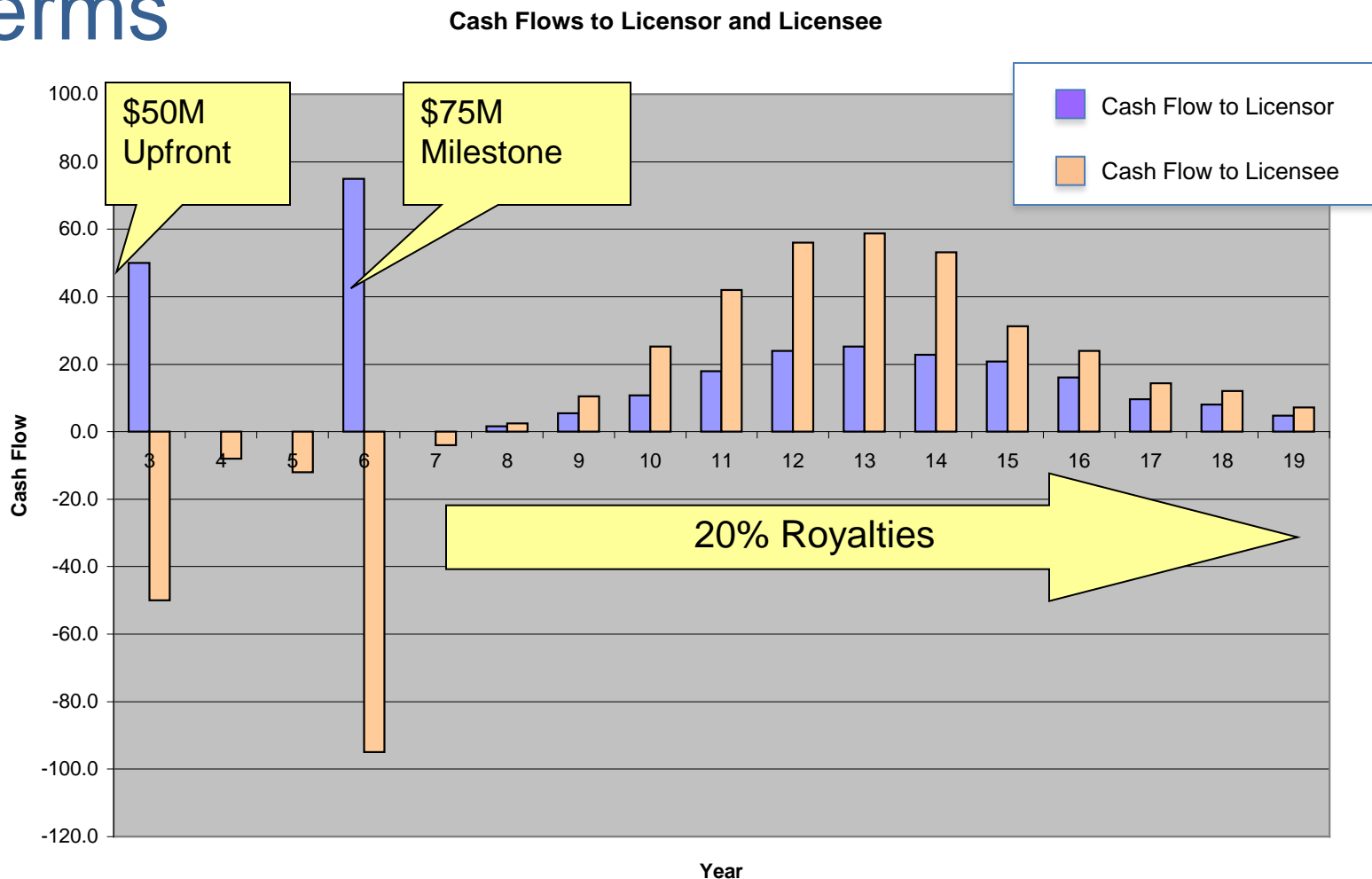
- Think of total product value (based on risk-adjusted net present value of cash flows) as a pie



- Pie gets split between the licensor and the licensee in the form of deal terms



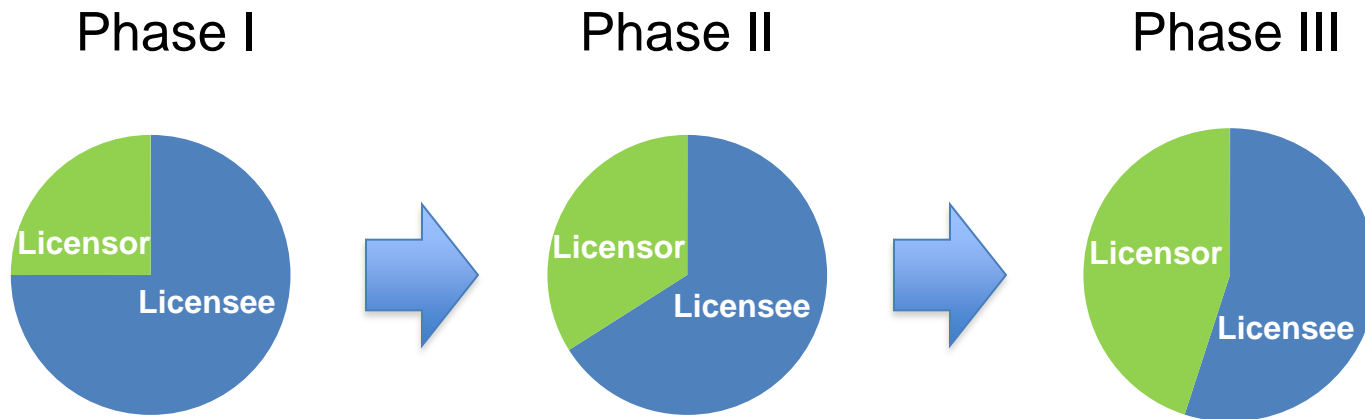
Expected Cash Flows Reflect Licensing Terms





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As a product moves forward in development, share to licensor increases.



Why? For a variety of reasons, but primarily because of scarcity—there are a lot fewer available Phase III assets.



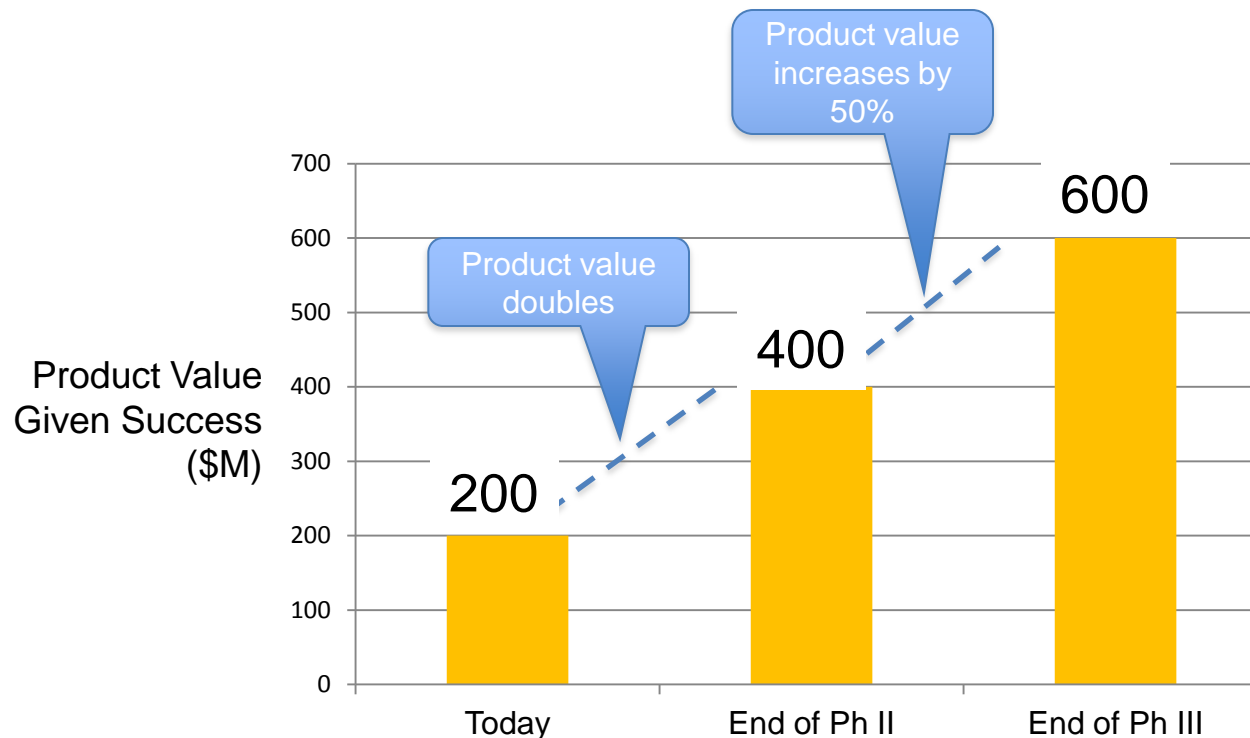
There's a Range in this Split – Why?

- Concept of “Strength of Negotiating Position”
- Factors include:
 - Interest level / number of bidders
 - Atypical relative contributions of licensee vs. licensor
 - Relative knowledge of market conditions
 - Relative strength of negotiating skills
 - Financial strength / distress of either party



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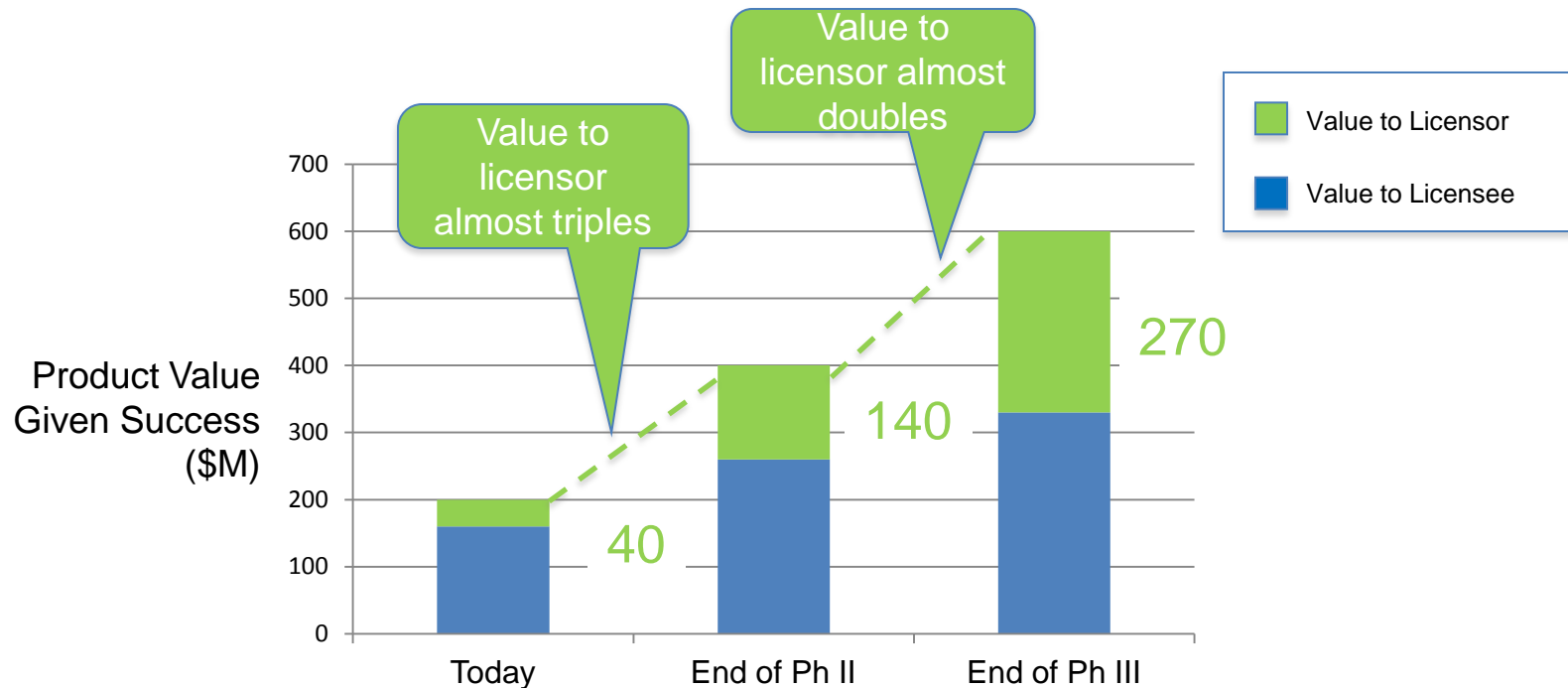
Key implication: product value increases substantially from a successful trial...





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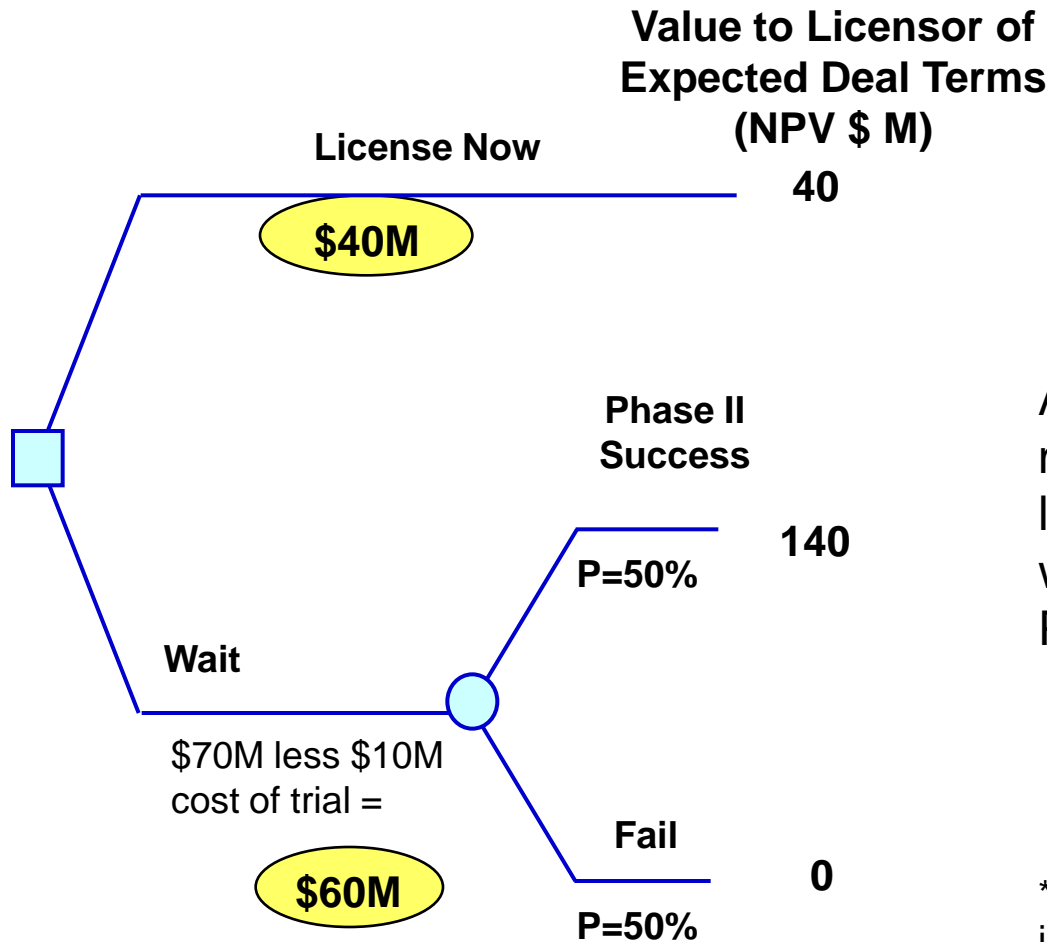
... But value to licensor increases by even more





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Application: License Now or Wait?



Assuming you can raise money on favorable terms*, licensors should consider waiting to license until after Phase II.

* Analysis doesn't yet include dilution or discounting on future deal



Summary

- Valuation methodologies
- Valuation concepts
- Link between valuation and deal terms (splitting the pie)
- Think Win-Win



Valuation Methodology: A Powerful Tool

- Evaluating and negotiating licensing deals
- Assessing value of programs
 - Selecting and prioritizing
 - Budgeting and monitoring
- Financing and investor relations
- M&A



FINANCE CONCEPTS IN LICENSING

Valuation Methodology

John Selig, Woodside Capital Partners

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Building a Business Development Model

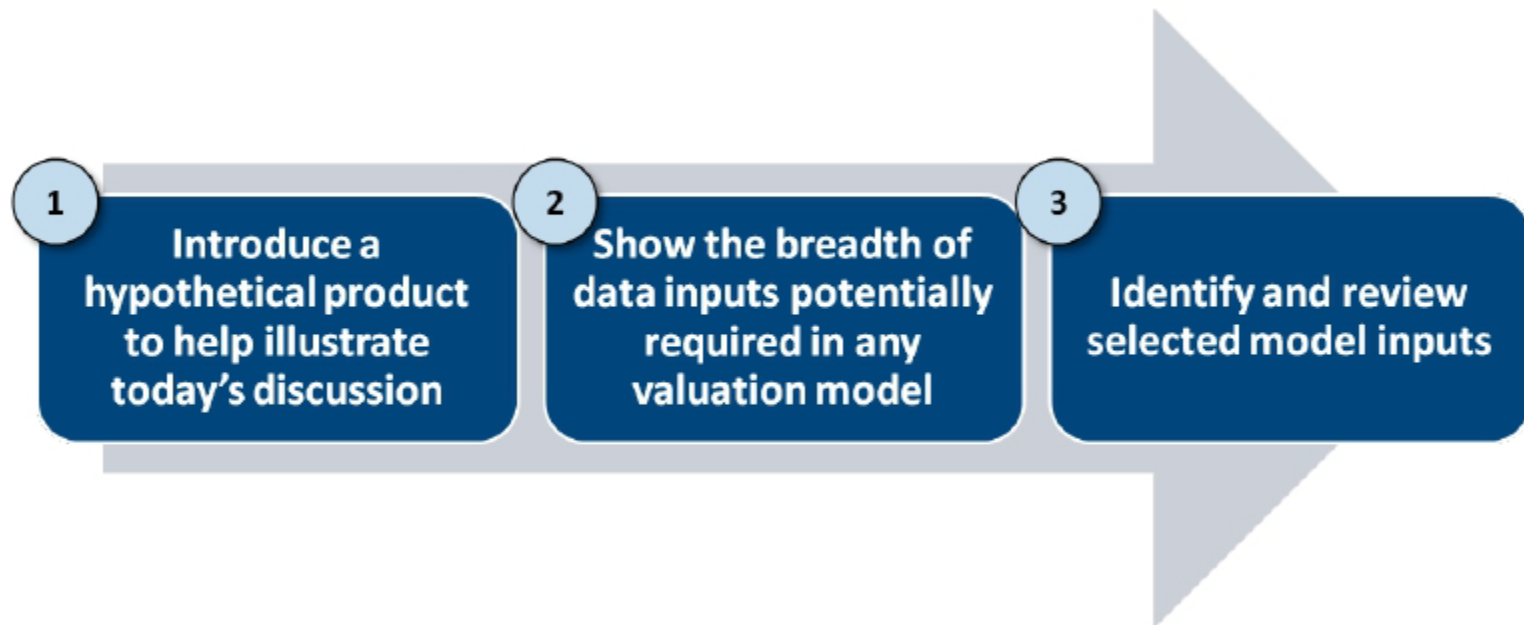
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Business Development Basics Course

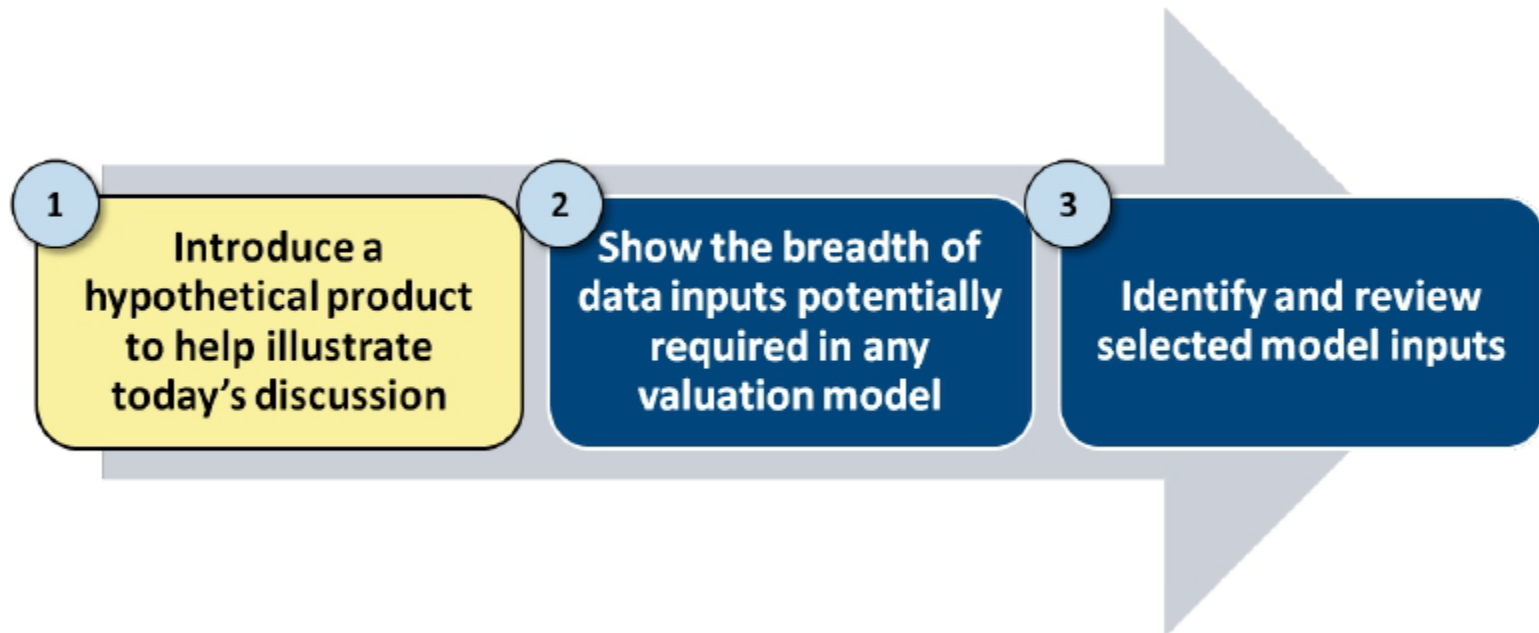
The next section of today's discussion will be to arm you with knowledge about the key data sources to use when building valuation models and to alert you to common mistakes that can occur along the way.





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We will first provide you with the details of a hypothetical product that will help guide today's discussion.





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As we think about the key inputs to building a valuation model and the data sources used to generate those inputs, it will be helpful to reference a hypothetical product.

- Our hypothetical product, “Zaxxon,” is a molecule currently in development for moderate to severe Crohn’s disease.
- It has the potential to be a very effective medication, but it comes with some side effects that we can assume will relegate it to always be a later-line therapy.
- We expect this product to enter phase III trials in October 2012.
- For the sake of simplicity we will imagine that we are only interested in the potential value of this product in the US.
- The drug is expected to be prescribed almost exclusively by specialists (gastroenterologists).
- Patent expiration for Zaxxon is expected to occur in early 2024.

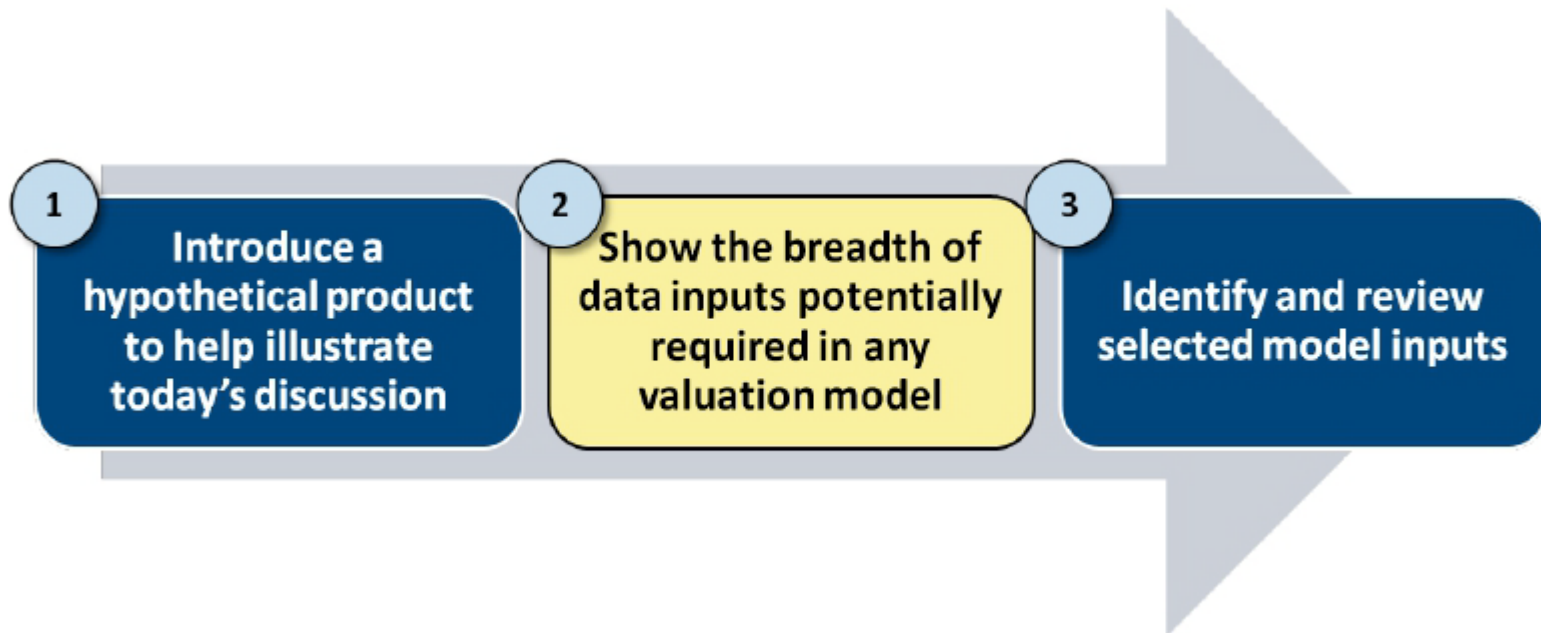
Our initial estimates for Zaxxon show a peak-year revenue of almost \$200 million and a net present value of \$65 million. We will now take time to understand some of the data sources that can go into such estimates.

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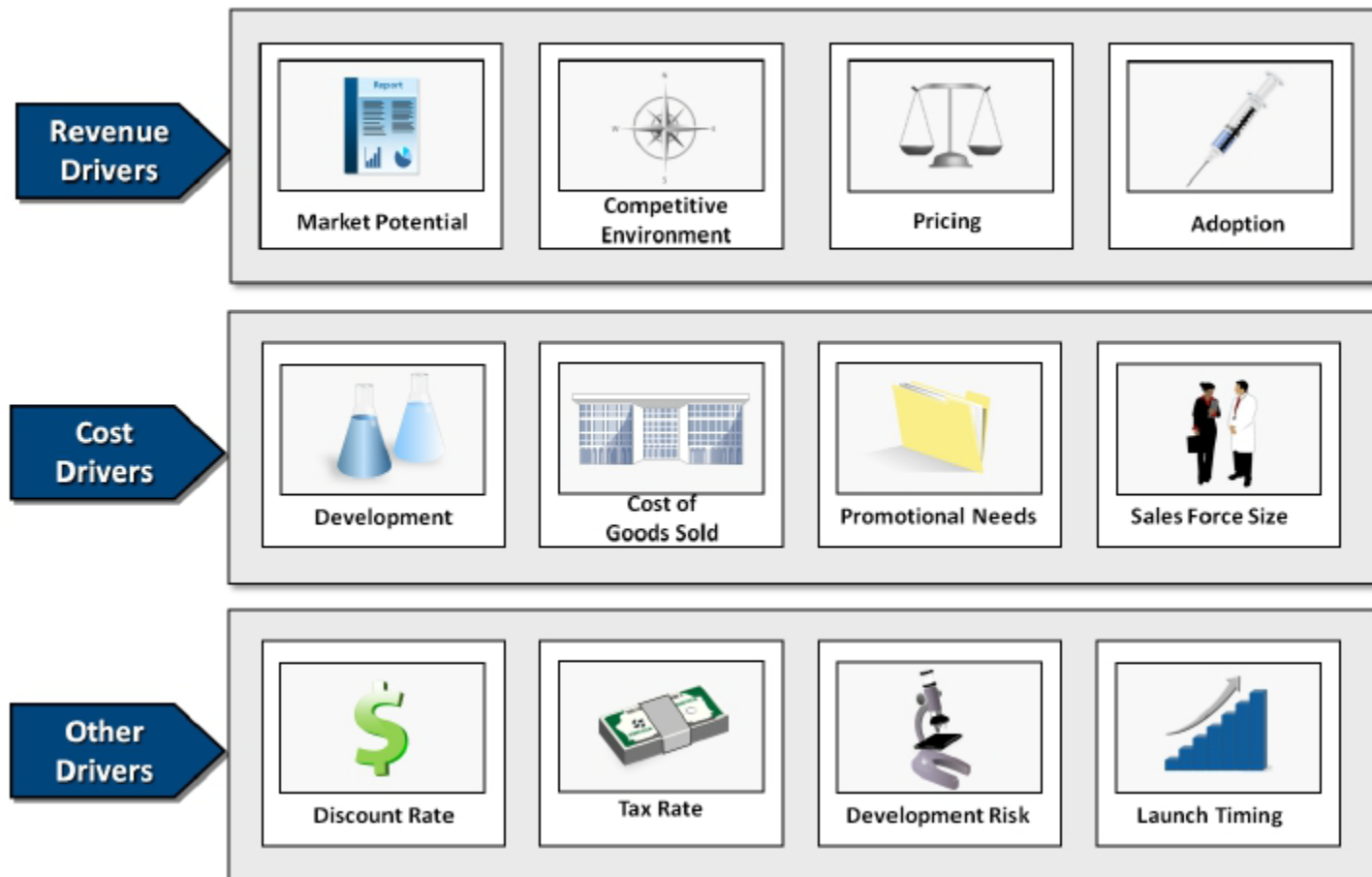
Building a valuation model requires you to make assumptions for a number of different forecast drivers.





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Model inputs can be divided into three segments: revenue, cost, and other, which account for inputs that are neither revenue nor cost drivers.





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When developing valuation models, it is important to remember that the forecast estimate is only as good as the assumptions that go into it. Significant time must be invested in identifying appropriate data sources that can support valid forecast assumptions.

Revenue Inputs

- Patient flow
- Product adoption
- Price of therapy
- Reimbursement
- Payer access
- Length of therapy
- Number of episodes per year

Cost Inputs

- Development
- Sales force
- Pre-launch marketing
- Post-launch marketing
- Costs of goods sold
- Rebates/discounts
- NDA application
- Milestone payments

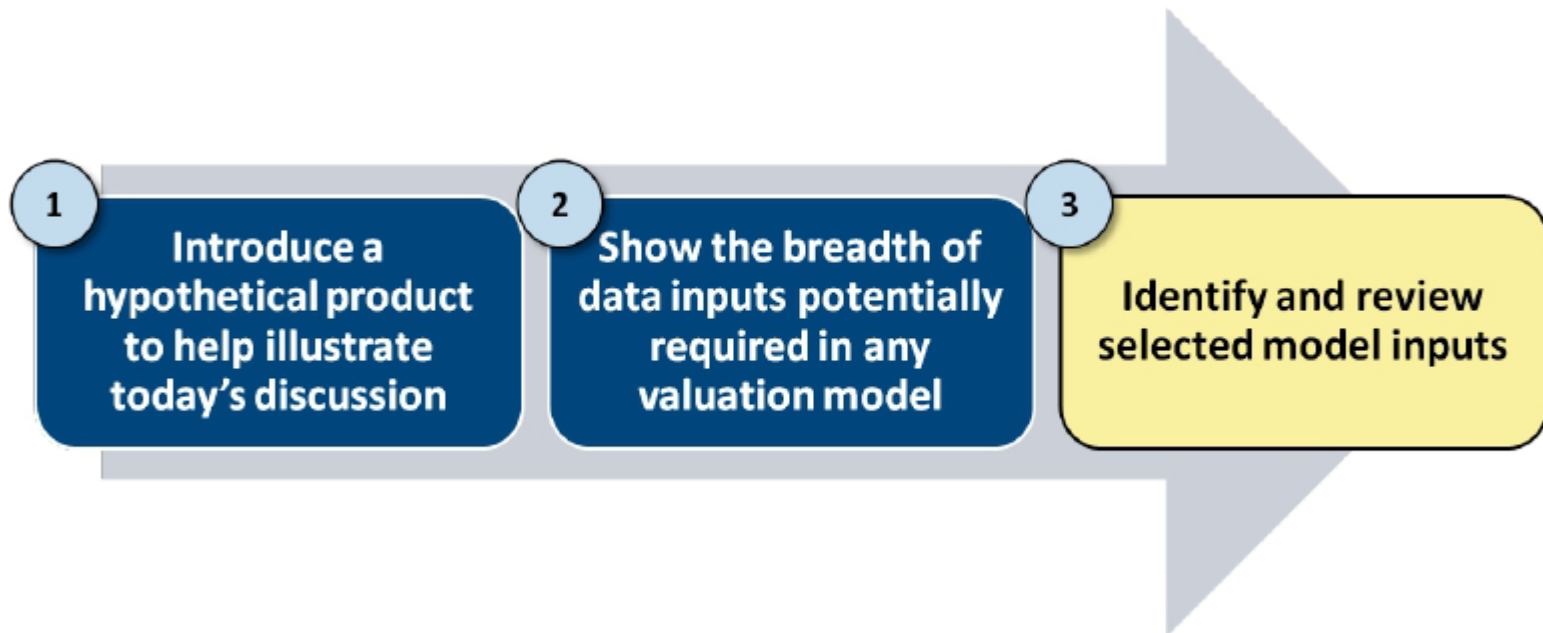
Other Inputs

- Discount rate
- Tax rate
- Development risk
- Launch timing



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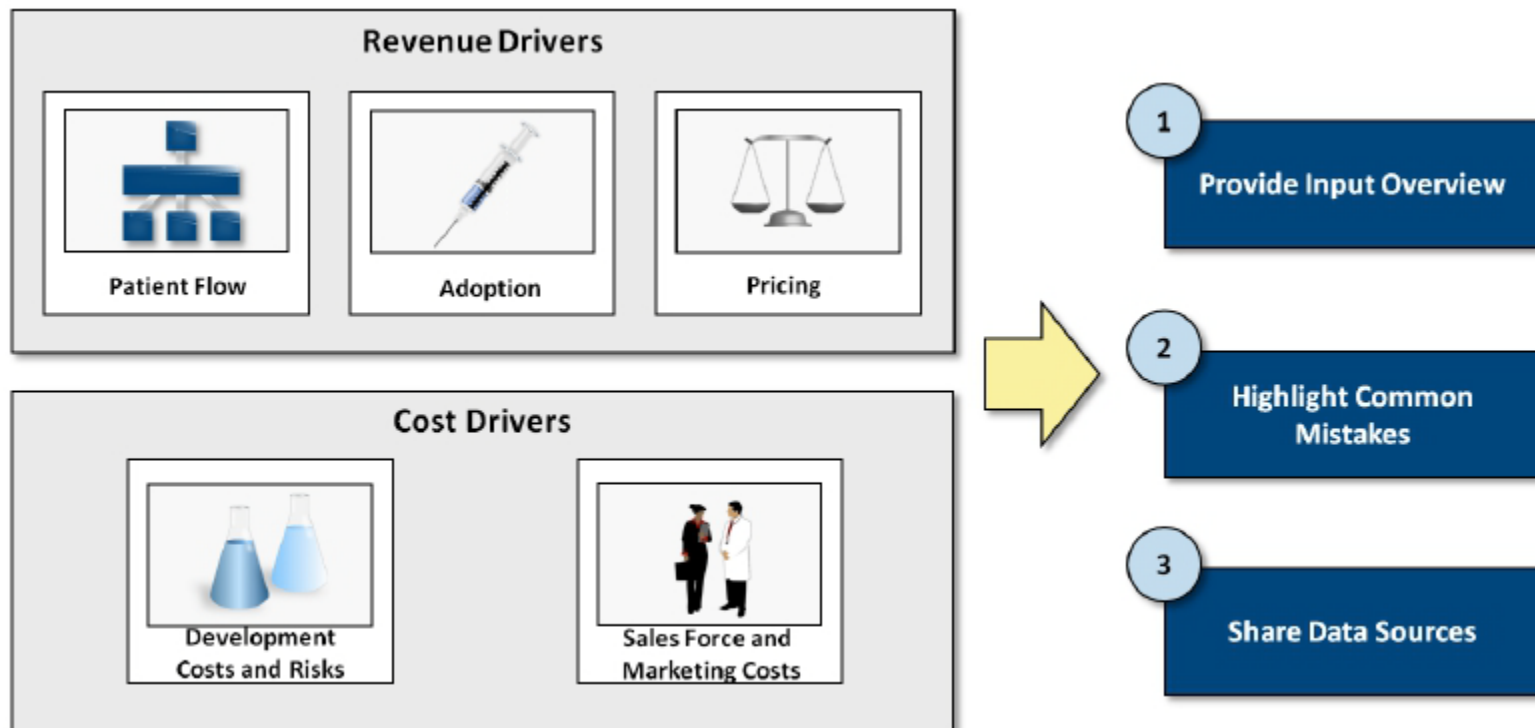
Our remaining time will be focused on reviewing several key model inputs.





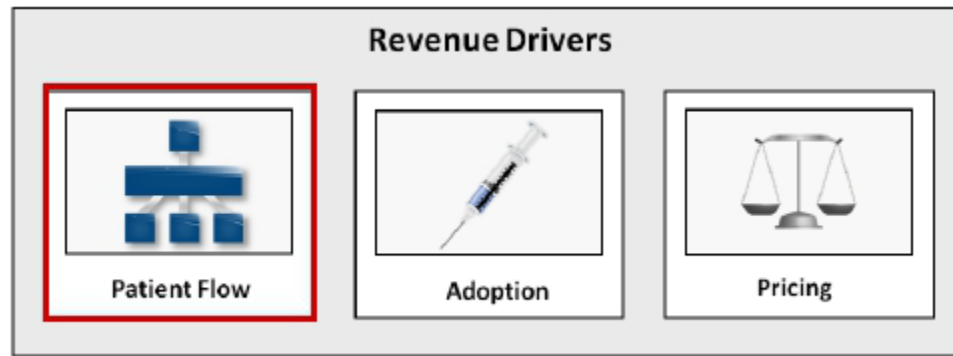
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Due to our limited time we have focused our discussion on a few important inputs that go into a valuation model. For each, we will provide an overview, highlight mistakes commonly made with the assumption, and share helpful data sources.



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We will first explore three key drivers of a revenue forecast. The first component we will discuss is patient flow.

[illegible]



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A starting point for understanding the patient flow is often the US census population data. From there, we then segment the relevant patient population based on primary and secondary research.

Population	Total Population in US	300M
Prevalence Rate	Crohn's Prevalence (.17%)	520K
Segmentation by Disease Severity	<i>Moderate to Severe Crohn's Population (60%)</i>	312K
Diagnosed and Treated Rate	<i>Diagnosed and Treated Moderate to Severe Crohn's Population (90%)</i>	281K
Segmentation by Line of Therapy	<i>Moderate to Severe Crohn's Prevalence Not on 1st-Line Therapy (80%)</i>	225K

Overall Population



Specific Subgroup of Patients
Who Are Candidates for This
Drug



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Using potentially biased sources and not pinpointing the appropriate patient population can overestimate Zaxxon's product valuation.

Patient Flow Component	Common Mistake	Instead You Should...
Prevalence	Using only figures cited in the press, by patient advocacy groups, or industry participants	<ul style="list-style-type: none">▪ Combine prevalence estimates from a number of sources.▪ Consider the potential incentives and biases of particular sources.▪ Segment the patient universe according to Zaxxon's product profile.
Segmentation by Disease Severity	Including patients whose disease severity does not match Zaxxon's profile	
Diagnosed and Treated Rate	Including all patients with a condition, not just those whose condition warrants treatment by a physician	
Segmentation by Line of Therapy	Including patients whose treatment status does not match Zaxxon's profile	



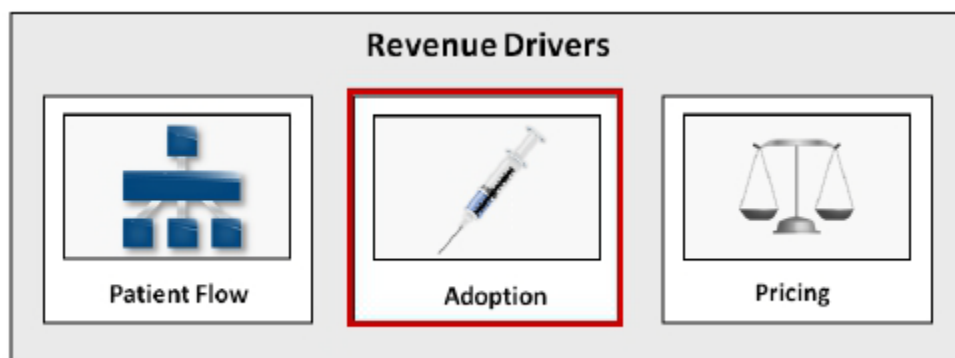
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There are a number of sources that can be consulted when constructing a patient flow. Ideally, each assumption will be verified through multiple sources.

Secondary Research			Primary Research With Appropriate Stakeholders
Free and Publicly Available (Easy-to-use, but be mindful of source quality)	Syndicated Data (One-time purchases or subscriptions)	Data Service Companies (High quality but potentially expensive)	
<ul style="list-style-type: none">• National Institute of Health website [<i>prevalence</i>]• World Health Organization website [<i>prevalence</i>]• Journal articles [<i>prevalence, segmentation, diagnosed and treated rate</i>]• Patient advocacy websites [<i>prevalence</i>]• SEC filings and press releases of competitors [<i>prevalence</i>]• NHANES (CDC) [<i>prevalence</i>]• SEER database (NIH) [<i>oncology prevalence</i>]• National Hospital Discharge Survey (CDC) [<i>prevalence</i>]• US Renal Data System (ESRD)• International Agency for Research on Cancer [<i>international cancer prevalence</i>]	<p>Many may cover some or all dimensions of the patient flow. It is important here to check the source behind the source and to cross-reference inputs across multiple sources.</p> <ul style="list-style-type: none">• Datamonitor• Business Insights• Decision Resources• Analyst reports• DaVinci (oncology)• Some journal articles	<p>Script data for competitive products can help you refine and validate all dimensions of the patient flow.</p> <ul style="list-style-type: none">• IMS• Wolters Kluwer• Verispan• Timely Data Resources	<p>Primary research with physicians should be used to validate findings from secondary sources when possible.</p>

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We will next discuss key data sources for estimating product adoption for Zaxxon.

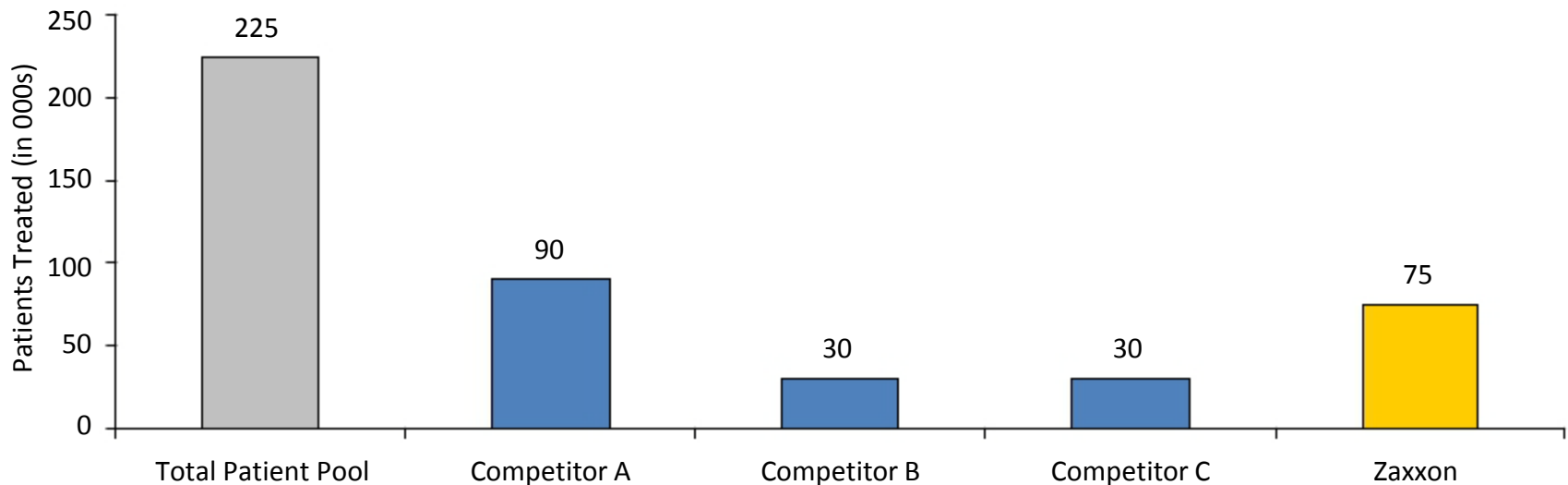
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After identifying the total potential patient population, we need to estimate the number of patients for whom physicians will prescribe Zaxxon.

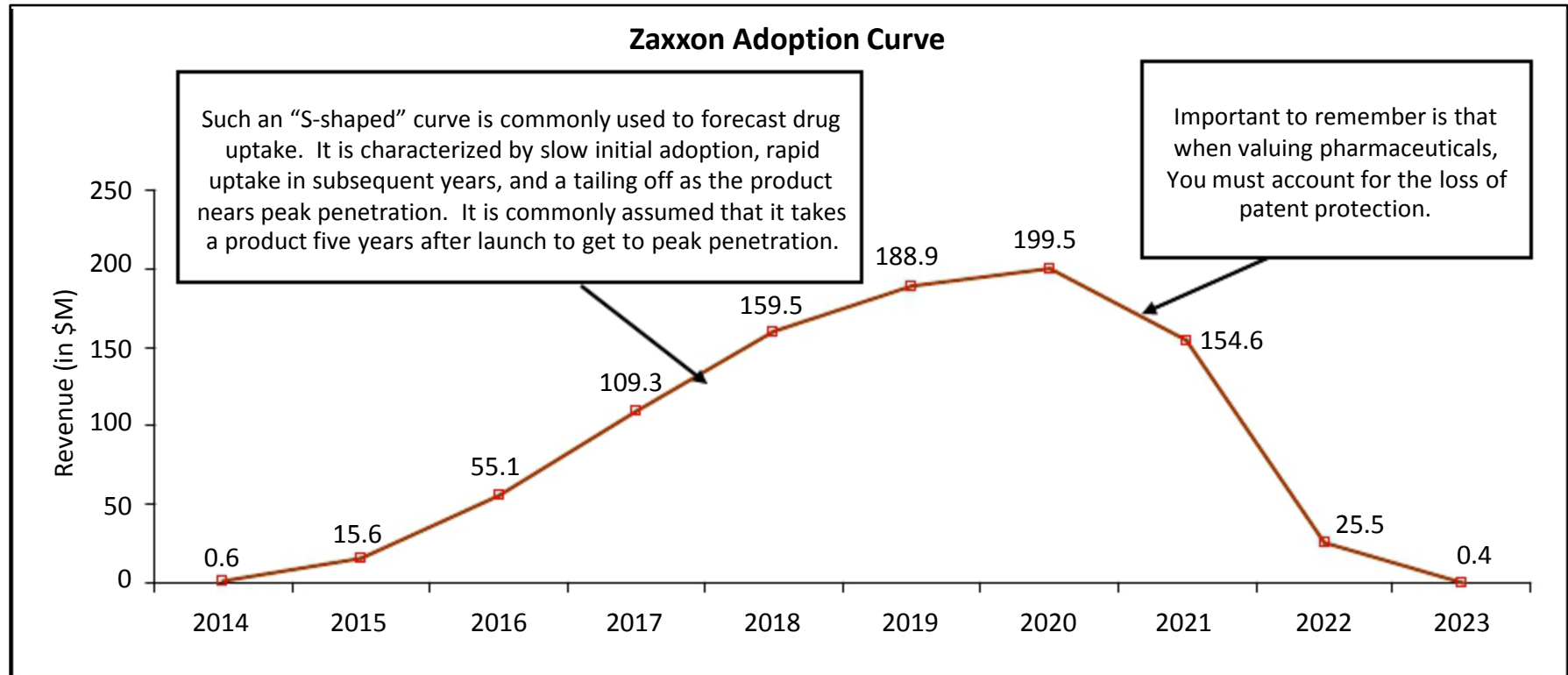
Crohn's Disease Competitive Landscape





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We must also assume an uptake curve for the adoption of Zaxxon. In this example we assume a five-year sigmoid curve.





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Even with primary market research with prescribing physicians, there are a number of common mistakes that can dramatically alter product valuation.

Common Mistake	Instead You Should...
Ignoring compliance	Do not forget to account for lost patients. A percentage of patients will experience insufficient efficacy and/or troublesome side effects with Zaxxon just as they do with other therapies.
Using an unrealistic product profile in market research	Share with physicians a target profile based on Zaxxon's clinical data. Overestimating or underestimating Zaxxon's efficacy, safety, and/or convenience can result in a misrepresentation of the drug's value.
Not considering future competitors when assessing the future market for Zaxxon	When forecasting the future market for Zaxxon, remember to account for future entrants. In physician market research ask physicians about their potential use of Zaxxon in light of current and future competitors.
Unrealistic product adoption timeline	Base Zaxxon's uptake curve on the unmet need and competitive environment of the market you are forecasting.



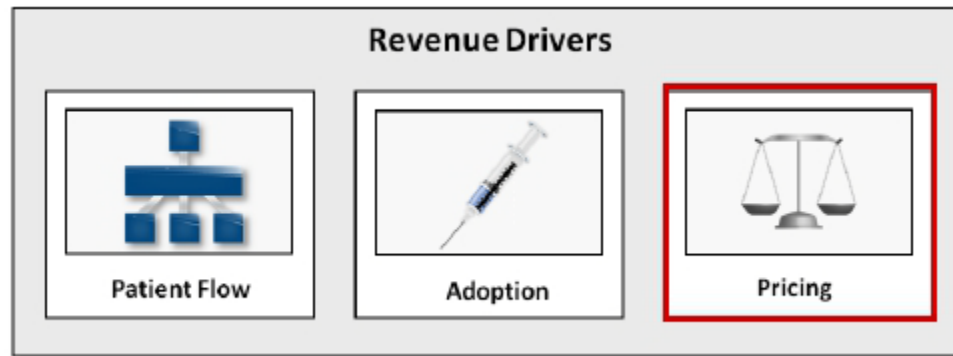
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Estimates for the adoption rate should be grounded in primary market research with prescribing physicians but can be validated through secondary research.

Secondary Research			
Free and Publicly Available (Easy to use but be mindful of source quality)	Syndicated Data (One time purchases or subscriptions)	Data Service Companies (High quality but potentially expensive)	
<ul style="list-style-type: none">▪ SEC filings and press releases of competitors may provide historical and current sales of competitive products▪ If primary research is not feasible, an assessment of the competitive landscape and a comparison of competitive products against Zaxxon can be a starting point to estimating an adoption rate for Zaxxon▪ Some analyst reports▪ FDA Orange Book [patent life]	<p>Analyst and industry reports can lay out the current competitive environment for Crohn's disease, which can help you profile competitive products along with Zaxxon in your primary market research. Sources include:</p> <ul style="list-style-type: none">▪ Datamonitor▪ Decision Resources▪ BCC Healthcare▪ Arrowhead Publishers▪ Visiongain Intelligence▪ Business Insights▪ Life Science Analytics▪ Med Ad News	<p>Data companies, including Wolters Klower and IMS, can provide historical sales trends on analog products that could enable you to construct adoption curves specific to Zaxxon.</p>	<p>Estimates for an adoption rate for Zaxxon should be generated through market research with appropriate physicians. Sharing Zaxxon's product profile with physicians can give an early sense for their likely adoption once Zaxxon is launched.</p>

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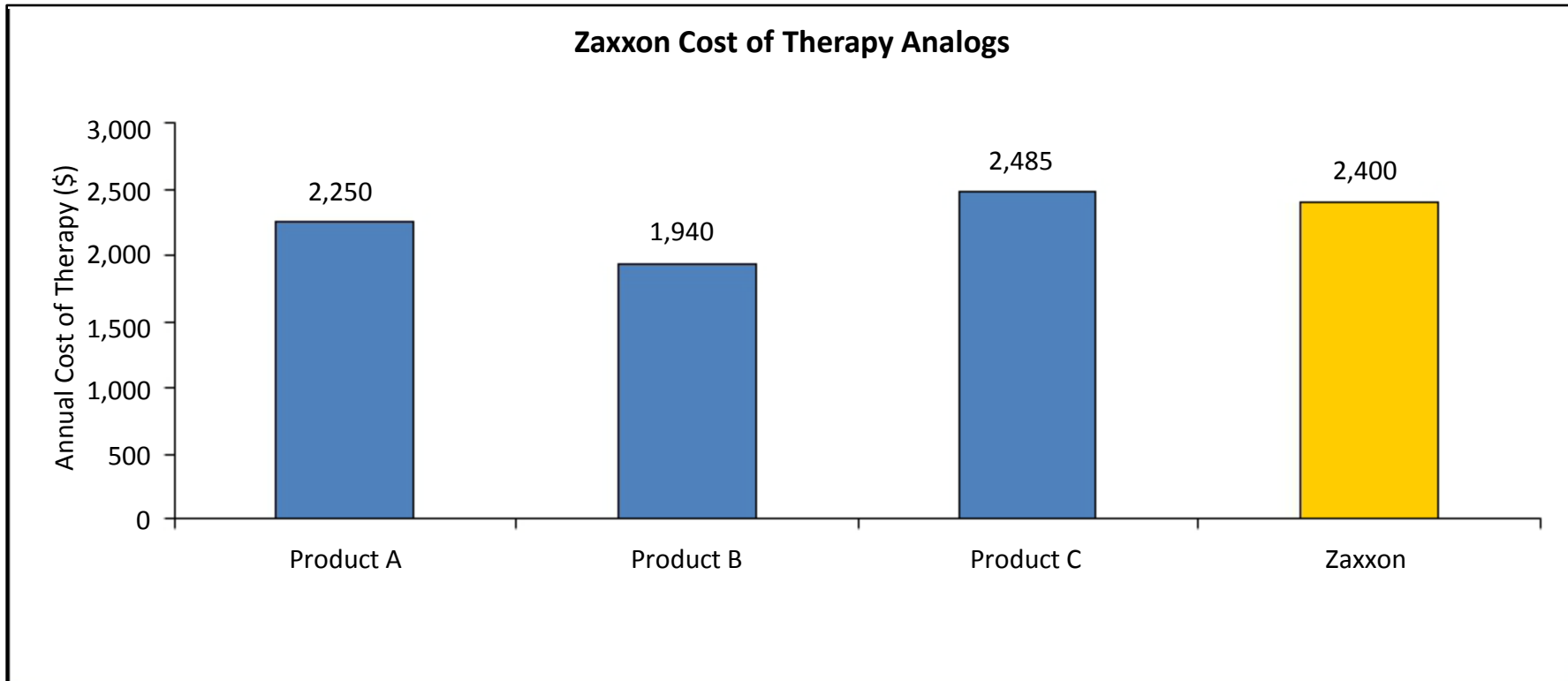
The final step in determining revenue is to estimate the cost of therapy and adjust for any potential payer restrictions.

[illegible]



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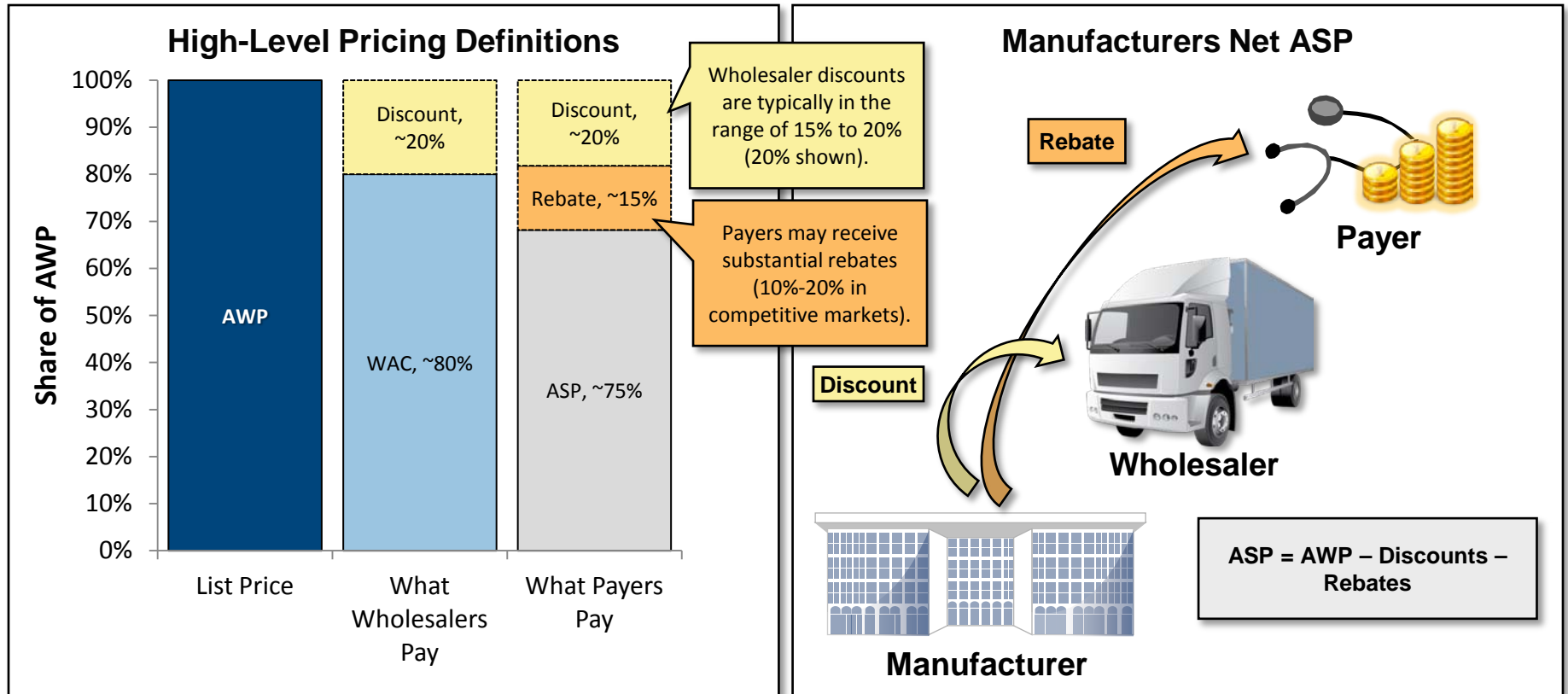
When a product is not internal to your company, you may have to estimate the price using the costs of analog therapies as a proxy.





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We need to know the price of a drug if we are to estimate its revenue. Be aware that “price” is a simple word with multiple meanings. Price may be expressed in terms of average wholesale price (AWP; “list”), wholesale acquisition cost (WAC; “wholesale”), and Average Selling Price (ASP; “net”).



We need to know ASP for the financial models. CMS (<https://www.cms.gov/McrPartBDrugAvgSalesPrice/>) now publishes ASP for drugs sold in the US.



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Using inappropriate product analogs, ignoring price rebates, and not taking into account the influence of generics are all common mistakes in estimating price.

Common Mistake	Instead You Should...
Using the wrong analogs	Make sure you identify appropriate analogs based on similar efficacy, safety, and method of administration.
Ignoring rebates	Account for potential rebates in the sales price of your drug.
Not paying attention to the generic status of competitive products	Research the remaining patent life of competitive products. If one or more products go generic during your forecast period, it could have a dramatic impact on your pricing power.



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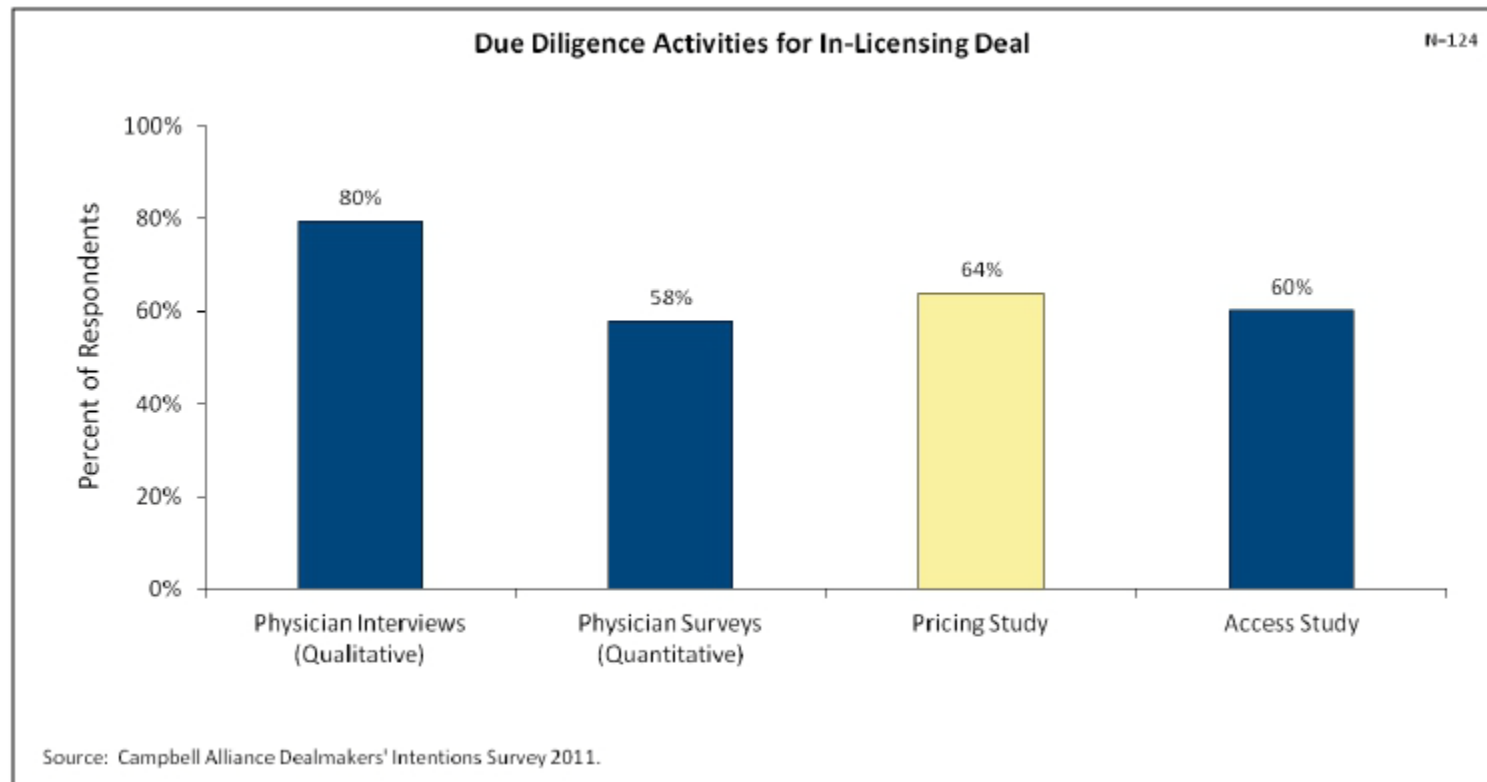
There are a number of potential sources to use to identify potential analog products for pricing and to find the prices for those analog products.

Secondary Research			Primary Research with Appropriate Stakeholders
Free and Publicly Available (Easy to use but be mindful of source quality)	Syndicated Data (One time purchases or subscriptions)	Data Service Companies (High quality but potentially expensive)	
<ul style="list-style-type: none">▪ Mail order prescription websites▪ Center for Medicare and Medicaid Services (CMS) – ASP Database▪ Epocrates.com (formulary data)	<ul style="list-style-type: none">▪ Medi-Span – Price Rx®▪ First Databank – Pricepoint Rx™▪ Red Book▪ Medispan (formulary data) <p><i>Syndicated publishers with pricing focused materials:</i></p> <ul style="list-style-type: none">▪ Decision Resources▪ Cutting Edge Information▪ Visiongain Intelligence	<ul style="list-style-type: none">▪ Wolters Kluwer – Can provide current and historic pricing information by product	



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Based on the Dealmakers' Intention Survey, pricing analysis in addition to physician analysis is becoming more of the norm when evaluating in-licensing opportunities.





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Example of a bad revenue analysis from a Wall Street Analyst

US Market	2012	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
<i>(All figures in thousands except prices)</i>											
# Patients eligible for treatment	3000										
% Diagnosed and treated	20%										
#Patients actually treated	600	654	713	777	847	923	1,006	1,097	1,196	1,303	1,420
Growth %	9%	9%	9%	9%	9%	9%	9%	9%	9%	9%	9%
% Market Share		0%	3%	6%	9%	12%	15%	15%	15%	15%	15%
# Patients treated		2	21	47	76	111	151	165	179	195	213
Cost per treatment (6 months)		\$2,887	\$2,974	\$3,063	\$3,155	\$3,250	\$3,347	\$3,447	\$3,551	\$3,657	\$3,767
Price Increase			3%	3%	3%	3%	3%	3%	3%	3%	3%
Cost for one-year treatment		\$2,887	\$2,974	\$3,063	\$3,155	\$3,250	\$3,347	\$3,447	\$3,551	\$3,657	\$3,767
Total U.S. products sales		\$5,774	\$63,601	\$142,800	\$240,491	\$360,038	\$505,193	\$567,113	\$636,803	\$714,835	\$802,607
Growth YoY			1002%	125%	68%	50%	40%	12%	12%	12%	12%

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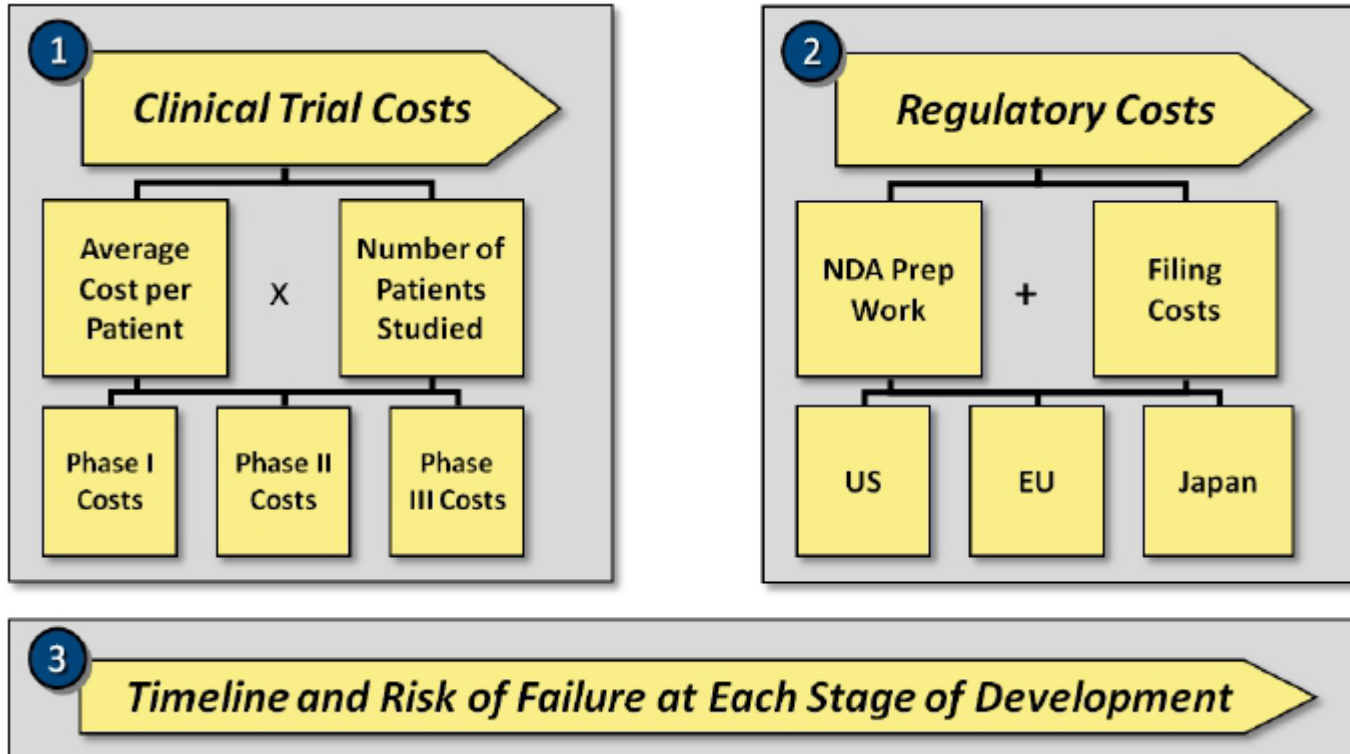
We will now discuss two important cost drivers: sales force costs and development cost (and risk). We will first discuss development costs and risks.

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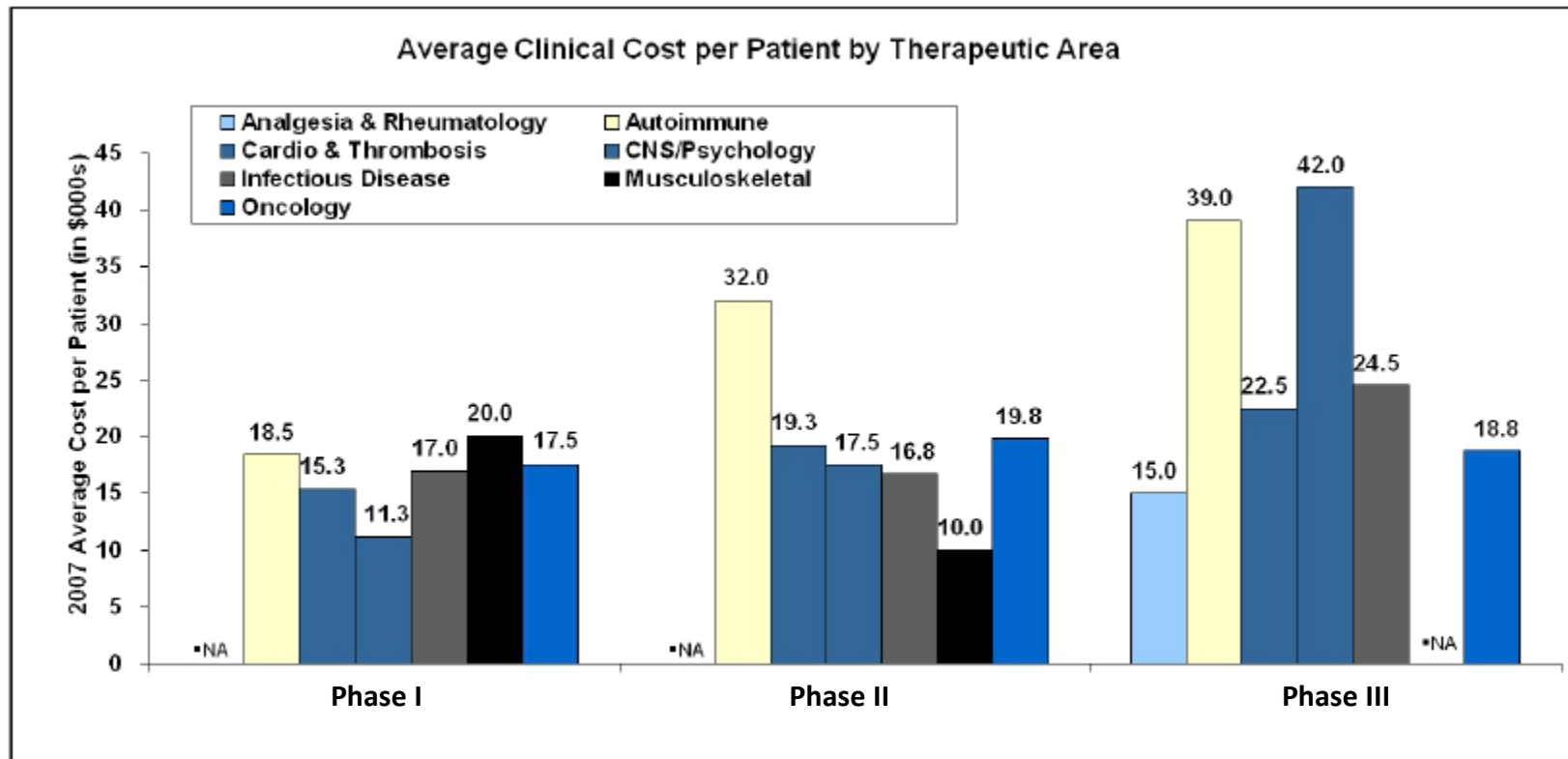
There is no substitute for a detailed, line-by-line forecast of clinical trial costs. However, when we lack a detailed forecast, we can use an estimation approach to forecast development costs.





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To estimate clinical costs, it is important to consider the therapeutic area of interest, the number of trials necessary, and the anticipated length of each trial.

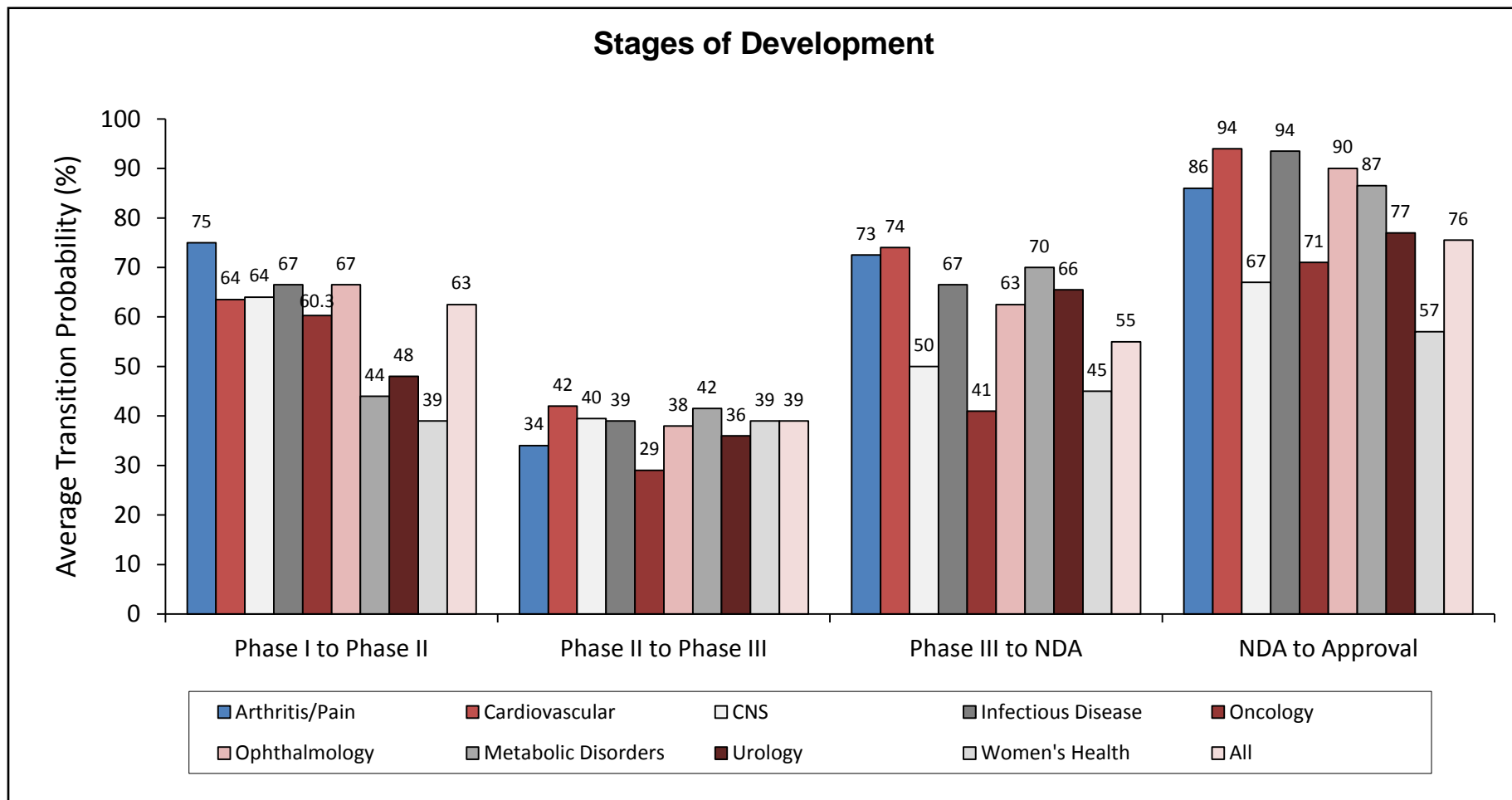


Source: Statistics on Drug Development. Costs/Complexity. Cited in Parexel's Bio/Pharmaceutical R&D Statistical Sourcebook 2008/2009.



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Clinical success is by no means a sure thing. Forecasting clinical



Source: Kola I, Landis J. Can the pharmaceutical industry reduce attrition rates? *Nat Rev Drug Disc.* 2004;3:711-715.



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Not properly accounting for development costs and risks can dramatically affect your valuation model as these occur in the early years of the forecast where valuation is most sensitive.

Common Mistake	Instead You Should...
Failing to account for development risk	In your model you need to account for the scenario where the drug fails overall, eliminating all subsequent cash inflows and outflows.
Not accounting for potential trial failures, especially in areas with high placebo response rates	Failed trials still cost money. Account for the possibility that your drug may need additional trials to account for failures by examining the trial history of competitive products.
Using unrealistic development timelines	The timing of cash flows is important in a valuation model, particularly in the early years. Be sure to assume a reasonable timeline, including for regulatory approval, when building a valuation model.



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There are several sources that may be used to help estimate development costs.

Factor	Secondary Research	
	Free and Publicly Available (Easy to use but be mindful of source quality)	Syndicated Data (One time purchases or subscriptions)
Estimating average cost per patient	<ul style="list-style-type: none">▪ Internal company data	<ul style="list-style-type: none">▪ Paraxel's Pharmaceutical R&D Statistical Sourcebook (provides data by phase and by therapeutic class)▪ Frost & Sullivan▪ Datamonitor▪ Kalorama Information▪ Business Insights▪ Center Watch
Estimating number of patients in trials	<ul style="list-style-type: none">▪ Internal company data▪ NIH▪ FDA Center for Drug Evaluation and Research▪ Clinicalstudyresults.org▪ Clinicaltrials.gov	
Estimating development risk	<ul style="list-style-type: none">▪ Internal company data▪ NIH▪ FDA Center for Drug Evaluation and Research	



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The more customized to your situation the better, but below are some general industry data that you may consider using in the absence of anything else.

Factor	Secondary Research	
	Free and Publicly Available (Easy-to-use but be mindful of source quality)	Syndicated Data (One-time purchases or subscriptions)
Estimating average cost per patient	<ul style="list-style-type: none">Internal company data	<ul style="list-style-type: none">Paraxel's
Estimating number of patients in trials	<ul style="list-style-type: none">Internal company dataNIHFDA Center for Drug Evaluation and ResearchClinicalstudyresults.orgClinicaltrials.gov	<ul style="list-style-type: none">Statistical Sourcebook (provides data by phase and by therapeutic class)Frost & SullivanDatamonitorKalorama Information
Estimating development risk	<ul style="list-style-type: none">Internal company dataNIHFDA Center for Drug Evaluation and Research	<ul style="list-style-type: none">Business InsightsCenter Watch

According to the NIH and FDA (as cited on the Mayo Clinic website), the following are estimates for trial sizes:
P1 = 20-80
P2 = 100-300
P3 = 1000-3000

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The final cost driver we will discuss is sales and marketing costs.

[illegible]



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It is important to first understand the concept of “deciling.” In sales force forecasts, a prescribing universe is often broken down into deciles based on prescribing levels.

Top Prescribers of CNS Market

Market Decile	Number of Prescribers	Cum. # of Prescribers	Cum. % of Prescribers	Cum. % of TRx
10	3,517	3,517	0.5%	10.0%
9	6,437	9,954	1.5%	20.0%
8	8,890	18,844	2.9%	30.0%
7	11,245	30,089	4.7%	40.0%
6	13,864	43,953	6.8%	50.0%
5	17,141	61,094	9.5%	60.0%
4	21,863	82,957	12.8%	70.0%
3	30,136	113,093	17.5%	80.0%
2	50,445	163,538	25.3%	90.0%
1	482,539	646,077	100.0%	100.0%

Composition of Top Prescribers

Market Decile	Number of Prescribers	Psych	PCP
10	3,517	2,845	425
9	6,437	2,992	2,879
8	8,890	2,321	5,705
7	11,245	2,051	7,920
6	13,864	2,011	9,983
5	17,141	2,129	12,152
4	21,863	2,626	14,493
Total	82,957	16,975	53,557



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A “reach and frequency” model can be used to estimate sales force costs.

A	Item	Value
	Details per Day	7
	Selling Days per Year	211
	Details per Year per Rep	1,477
	Cost per Year per Rep	\$150K

	Audience	US Gastroenterologists	Total
B	Number of Specialists	11,864	11,864
C	Frequency of Details	15 for deciles 9-10; 10 for deciles 6-8	
	Total Details	71,184	71,184
D	Share of Cost to Product	100%	100%
E	Required Reps	49	49
	Total Detailing Cost	\$7.35M	\$7.35M

Expected cost of field force

- A** Determined the typical fully-loaded field-force costs by market (and/or specialty) based on industry benchmarks
- B** Determined number of relevant specialists by market to be targeted for Zaxxon
- C** Determined the reach (i.e., *How many deciles to target?*) and frequency (i.e., *How often to target these deciles?*) based on internal company decisions
- D** Allocated share of detail to Zaxxon (based on expected positioning within detail call)
- E** Calculated the number of required reps and total detailing costs for Zaxxon



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There are a number of common mistakes that can be made across the different variables that go into a “reach and frequency” model.

Common Mistake	Instead You Should...
Not allocating the sales force costs across multiple products	If the sales force will be detailing multiple products to the same physicians, the sales force cost should be split accordingly.
Not using fully-loaded costs to estimate the cost of a salesperson	In addition to base salary and bonus, you must account for benefits. A rule of thumb is 2x salary and bonus to arrive at a “fully-loaded” cost.
Accounting for all physicians within a prescribing universe when forecasting sales costs	Typical sales efforts focus only on the top few prescribing deciles to get the highest return on investment. Include only those target physicians who are believed to be sales targets.



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There are several sources that can be consulted when building a “reach and frequency” model to estimate sales force costs.

Factor	Secondary Research			Primary Research with Appropriate Stakeholders
	Free and Publicly Available (Easy to use but be mindful of source quality)	Syndicated Data (One time purchases or subscriptions)	Data Service Companies (High quality but potentially expensive)	
A Determining fully-loaded field-force costs	<ul style="list-style-type: none">Internet research (salary.com)\$150K-\$250K is often used as fully-loaded cost	<ul style="list-style-type: none">Cutting Edge Information		Potentially validate data through primary research
B Determining number of relevant specialists to be targeted	<ul style="list-style-type: none">AMA website	<ul style="list-style-type: none">OECD website (provides European data)		
C Determine reach and frequency	<ul style="list-style-type: none">Internal assumption	<ul style="list-style-type: none">Cutting Edge Information	<ul style="list-style-type: none">Verispan can provide data on sales force size	Potentially validate data through primary research
D Allocate share of detail to Zaxxon	<ul style="list-style-type: none">Internal assumption			



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Example of a bad NPV analysis from a Wall Street Analyst

NPV Model

All figures in thousands (except per share figures)

Year	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Product sales	\$5,774	\$63,601	\$142,800	\$240,491	\$360,038	\$505,193	\$567,113	\$636,803	\$714,835	\$802,607
Operating expenses (75% of sales)	\$4,331	\$47,701	\$107,100	\$180,368	\$270,029	\$378,895	\$425,334	\$477,602	\$536,126	\$601,955
Net income (25% profit margin)	\$1,444	\$15,900	\$35,700	\$60,123	\$90,010	\$126,298	\$141,778	\$159,201	\$178,709	\$200,652
Net income*Likelihood of Success (80%) = E	\$1,155	\$12,720	\$28,560	\$48,098	\$72,008	\$101,039	\$113,423	\$127,361	\$142,967	\$160,521
NPV of EAT	\$377,536									
Cash by 2Q13E	\$26,000									
Total NPV	\$403,536									
NPV/Share	\$4.50									



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Modeling Best Practices

As we close today's presentation, there are a few important modeling best practices to discuss.

Managerial Recommendations

- Make sure you understand the market environment.
- Don't overcomplicate the risk assessment (more on this on the next page).
- Compare the results of your model with current products and recent deals.

Modeling Recommendations

- Use a standardized model template—starting from a blank spreadsheet for each new model is time-consuming and increases the potential for calculation errors.
- Use range names for input variables—avoid hard coding values in formulas.
- Use standardized formatting conventions that clearly differentiate user input from model calculations.
- When transferring model outputs to PowerPoint presentations, use the “Paste Special” utility—otherwise, your entire model will be embedded in the PowerPoint document.
- Create a page in your model to provide references for important inputs.