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The Value of a Biotechnology Business

March 7, 2017

Agenda

- ***Introduction***
- *Valuation*
- *Funding*
- *Exits*

Who am I?

- John Selig

- Co-founded and runs a boutique healthcare investment bank – Mavericks Capital in San Mateo

- Previously: management consultant with Strategic Decisions Group and M&A attorney with Weil Gotshal

- Teach similar course at BIO conference each year to biotech CEOs, venture capitalists and new business development executives and at Stanford Medical School for their entrepreneurship program
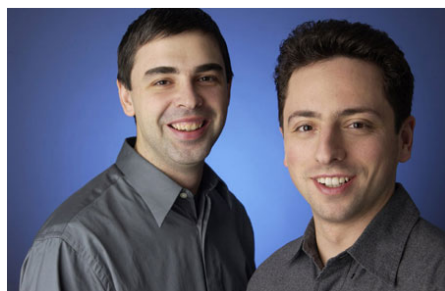
Agenda

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Why is life sciences valuation so complex?

Technology

 + **+** 9 months **=** Beta Launch (>90% POS)

Bio Pharma*

 + **+** 12-15 years **=** Product Approval (5% POS)

* Medtech (slightly) better

5

How much of this can you quantify and model?

What would that look like?

We need a valuation methodology that is credible and validated!

(and taken as seriously as your core science and development plan!)

Why is Accurate Valuation So Important?

- **To determine the value of your technology, products and business from the perspectives of**
  - Financeability
  - Attractiveness to a licensee

- **To determine optimal way to grow your company**
  - Raising dilutive capital vs.
  - Licensing vs.
  - Selling

- **To inform management decisions & frame the conversations that matter!**

The Good News:
This is Easier to Learn than the Science Underneath It

Valuation as Management Tool

- Supporting transactions

- Facilitating internal management decisions

- Supporting external pricing (e.g., stock price)

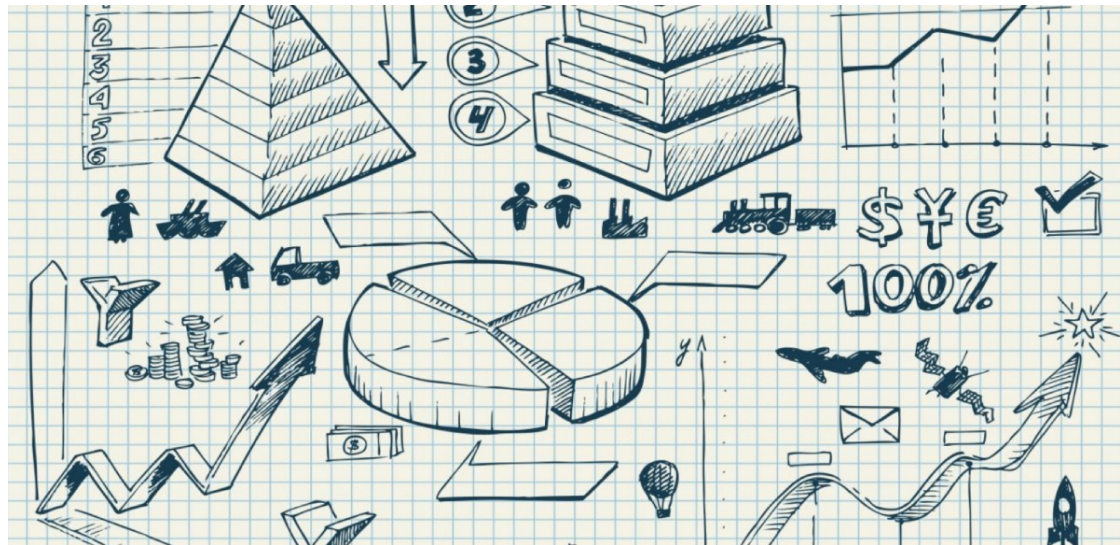# Acceptance of Results Depends on Alignment & Agreement

- Management

- Board of Directors

- Employees

- Prospective Licensing Party

- Corporate partners

- Investors

- Wall Street Analysts

Valuation Methodologies

1. Sunk Cost
2. Sum of Parts
3. Comparables
4. Discounted Cash Flow (DCF)
5. Risk-Adjusted NPV (rNPV)

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**

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

Issues
- 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

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- **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)

Benefits

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

Issues

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

Comparables

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

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

Issues
- **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

The Problem with Comparables

A better way to value:
cash flow forecast customized to the asset or company

Driving to Cash Flow and NPV

Gross Sales → Net Sales − Expenses = Pre-tax CF

Less rebates, returns, discounts, samples

Dev Costs
Manufacturing Costs
Marketing and Sales Costs
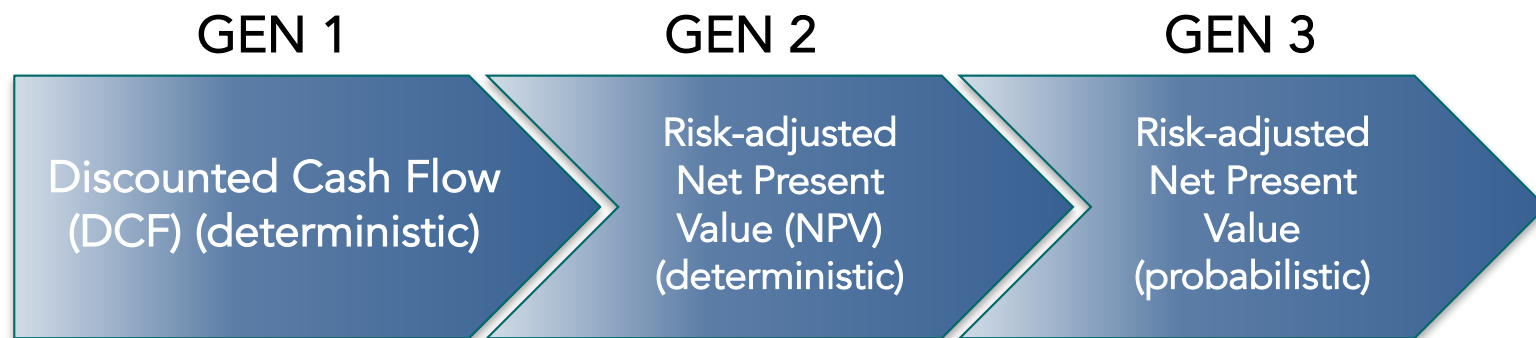Outgoing License Costs
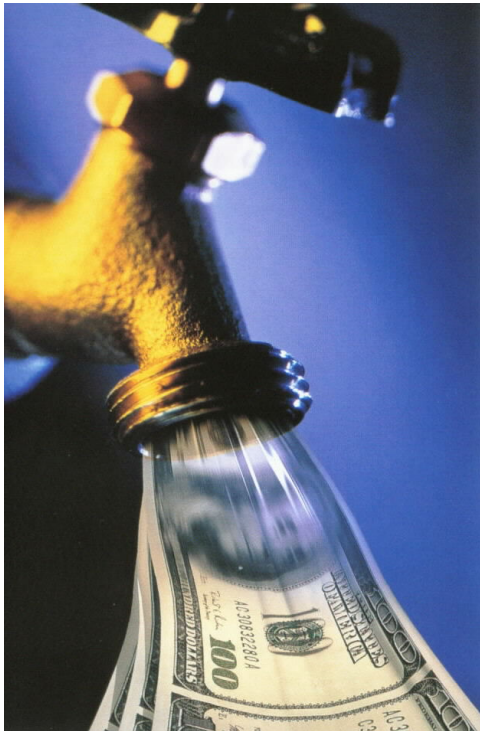
Discounted Cash Flow/Risk-Adjusted NPV

- **Approach: use <u>cash flow</u> as the key metric**
  - Cash flow is change in cash balance in a specified period of time
  - 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 concept: Risk-adjustment**
  - Value of an asset needs to be downward adjusted to account for forward-looking risk
- **Key concept: NPV (Net Present Value)**
  - Stream of forward-looking cash flow, discounted (i.e., time-adjusted) and in some cases risk-adjusted, to today

Evolution of Cash Flow Valuation

GEN 1

Discounted Cash Flow (DCF) (deterministic)

GEN 2

Risk-adjusted Net Present Value (NPV) (deterministic)

GEN 3

Risk-adjusted Net Present Value (probabilistic)

DCF Approach

- Uses a discount rate to account for both development risk and cost of capital (e.g., 20-30% rate for early stage products)

- **Deterministic**: Uses single point inputs and derives scenarios by varying only one or two inputs

- Example: Asset A is at the beginning of Phase II and is 5 years to market. DCF analysis would derive cash flow by:

  - Assigning a single high discount rate to the asset to account for risk

  - Assessing single numbers for every input and only varying, for example, price and market share

# DCF Approach (continued)

Forecast Cash Flow
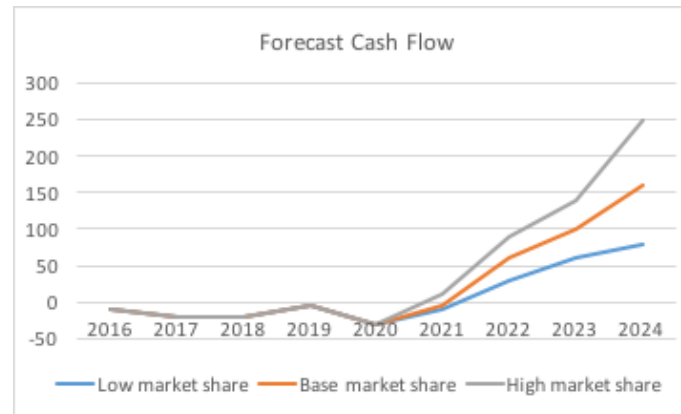
Benefits:

- Easier than additional customization—one size fits all

Issues:

- How do you customize different levels of risk from milestone to milestone?

- What weight to put on low/base/high market share scenarios?

- What about ranges on cost of Phase III, prevalence, diagnosis rate, market adoption, pricing, competitor entry, marketing

Risk-Adjusted Net Present Value (rNPV)

- Still using 3 market share scenarios only.

- But separating out the "one-size fits all" discount rate into two components:
  - Cost of capital
  - Stage probabilities of success
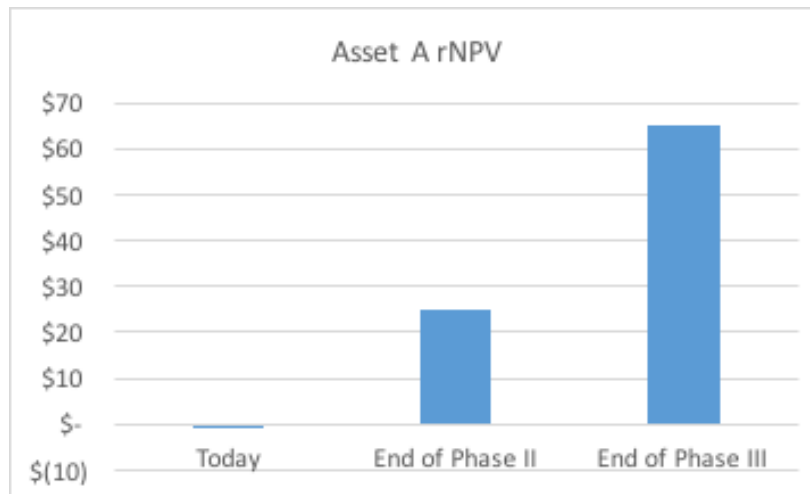
As Asset A moves forward in development and successfully completes clinical trials, it:

- Resolves risk

- Reduces forward-looking development spend

- Moves nearer to market

Why Might rNPV Be a Superior Methodology to DCF?

- **Distinguishes** risky, novel programs from less risky reformulation programs by using stage probabilities

- Allows much **more control** over customizing valuations to specific indications using probability of success benchmarks

- Allows determination of explicit risk to next milestone; **can see step-up in value** when get to the next phase

Deterministic vs. Probabilistic Models

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```
Discounted Cash Flow   →   Risk-adjusted Net   →   Risk-adjusted Net
(deterministic)            Present Value            Present Value
                           (deterministic)          (probabilistic)
```

Deterministic

- Risks are based on scenario analysis
- Costs are tied to those fixed scenarios
- Revenue scenarios typically involve a High, Low and Base Case

Probabilistic

- Can accommodate wide range of variables
- Each variable can have its own distribution curve (not fixed like high, low and base cases)
- Requires *Monte Carlo* simulation
- Results in probability curves for each variable and shows how each variable can affect one another!
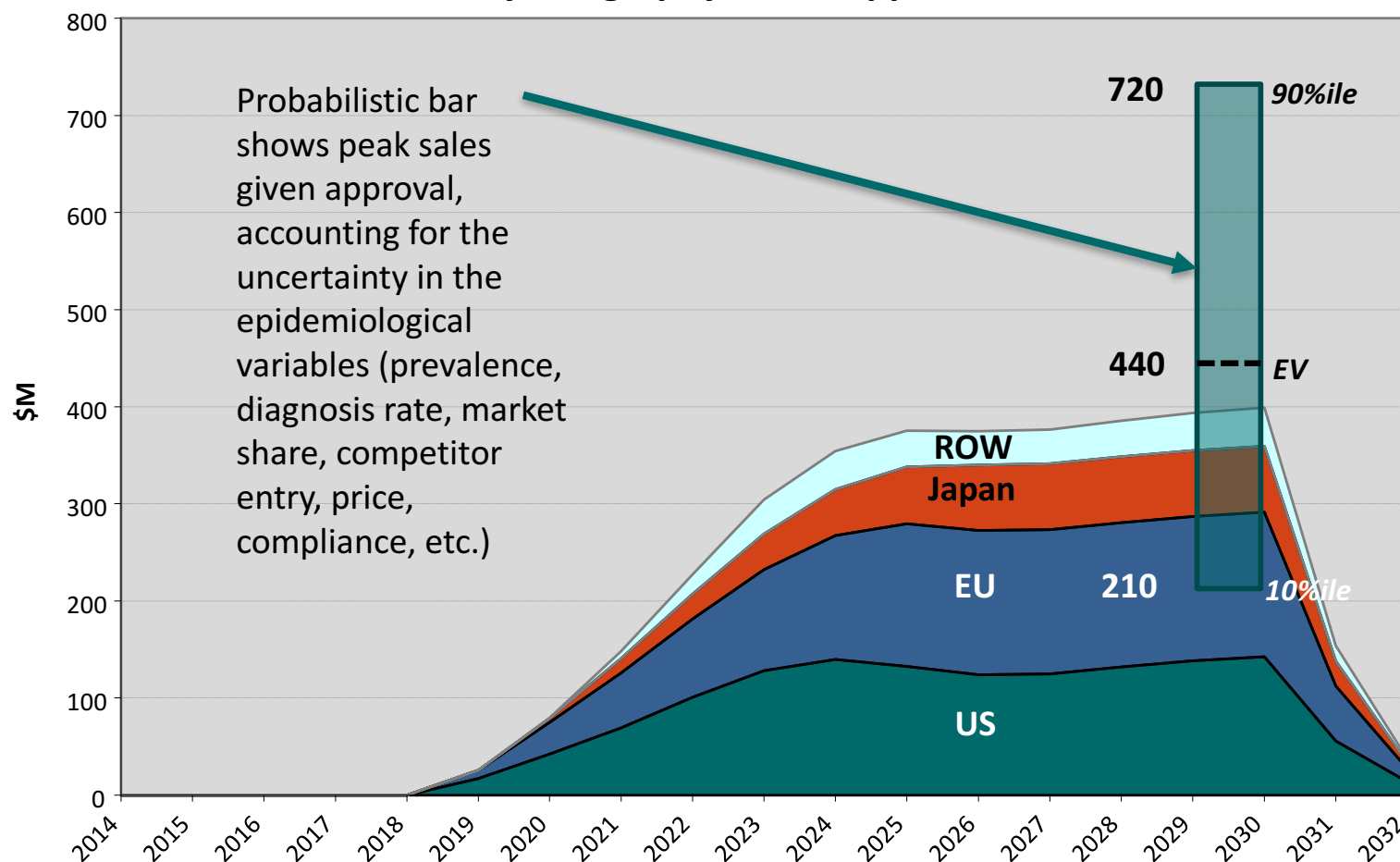
Deterministic vs. Probabilistic Models (continued)

Key benefit of probabilistic modeling is INFORMATION

- What's the probability of revenue being less than $100M by year 5?

- What's the impact on peak sales if fewer patients are diagnosed than expected?

- What's the likelihood of breaking even in 3 years?

- How likely are we to spend more than $50M on development costs?

Deterministic vs. Probabilistic Models (continued)

Asset B Base Case Sales by Geography Given Approval

Probabilistic bar shows peak sales given approval, accounting for the uncertainty in the epidemiological variables (prevalence, diagnosis rate, market share, competitor entry, price, compliance, etc.)

720 — 90%ile

440 — EV

210 — 10%ile

ROW
Japan
EU
US

Deterministic vs. Probabilistic Models (continued)

Sensitivity analysis allows determination of which assessments have greatest uncertainty impact on revenue or value
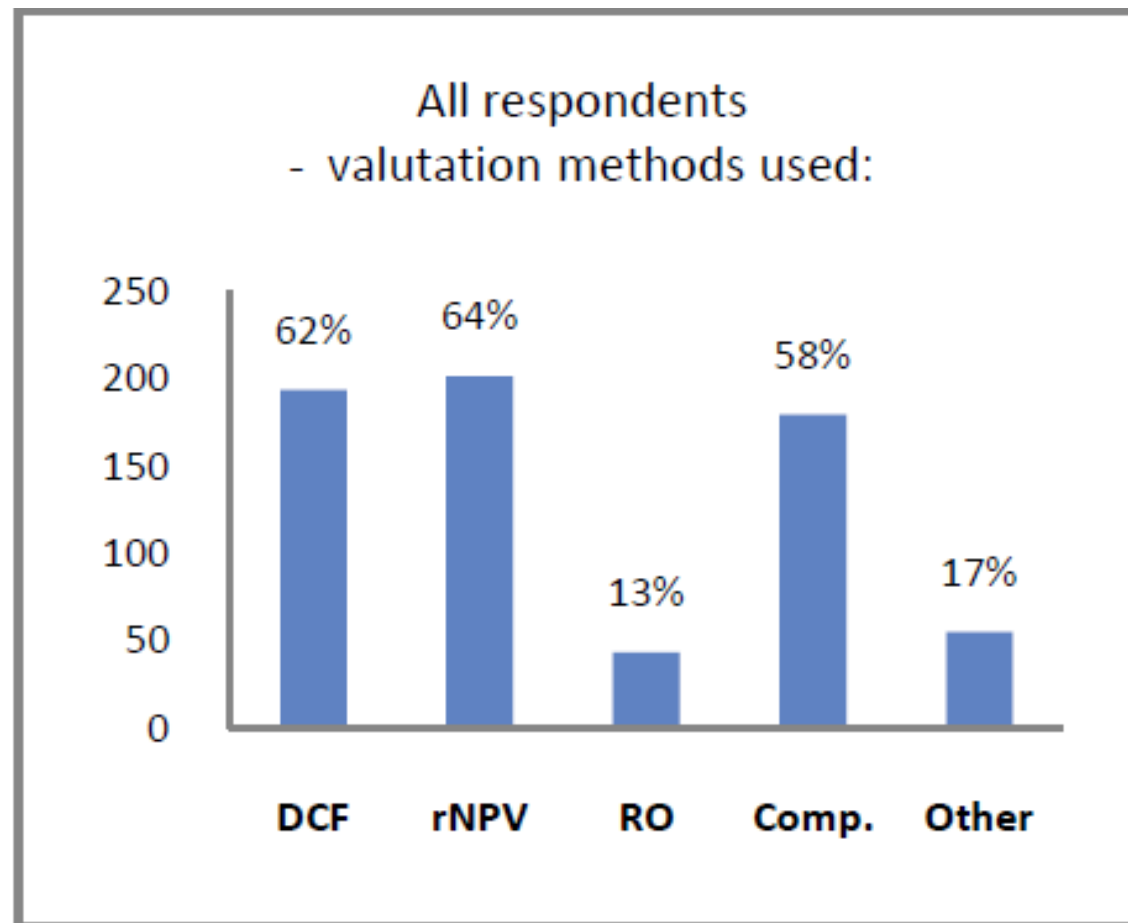

Peak revenue of Asset B ($M)

Results of Valuation Survey
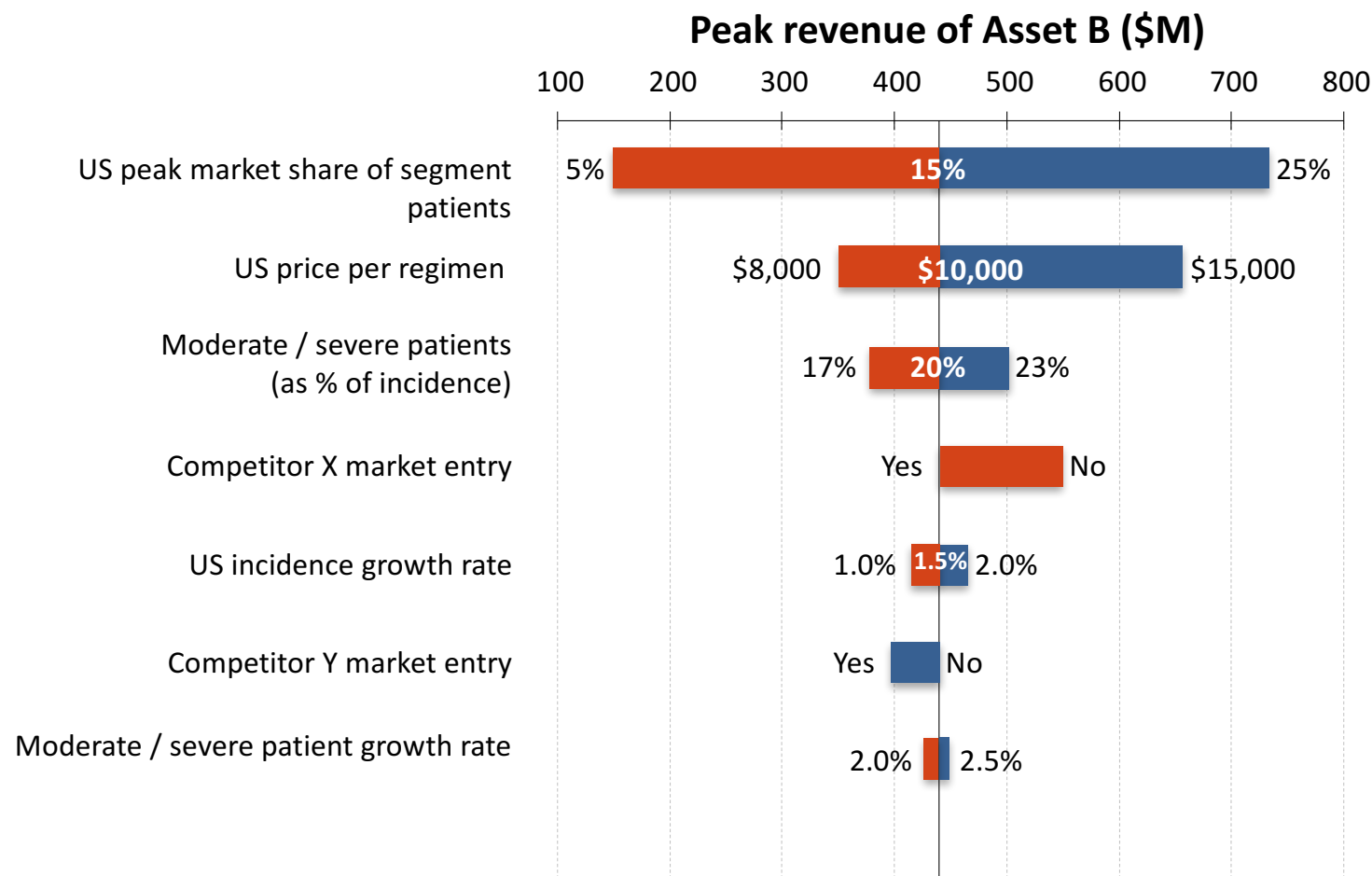
Multiple approaches:

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

Which of these valuation methodologies are used most often in life sciences analytics?
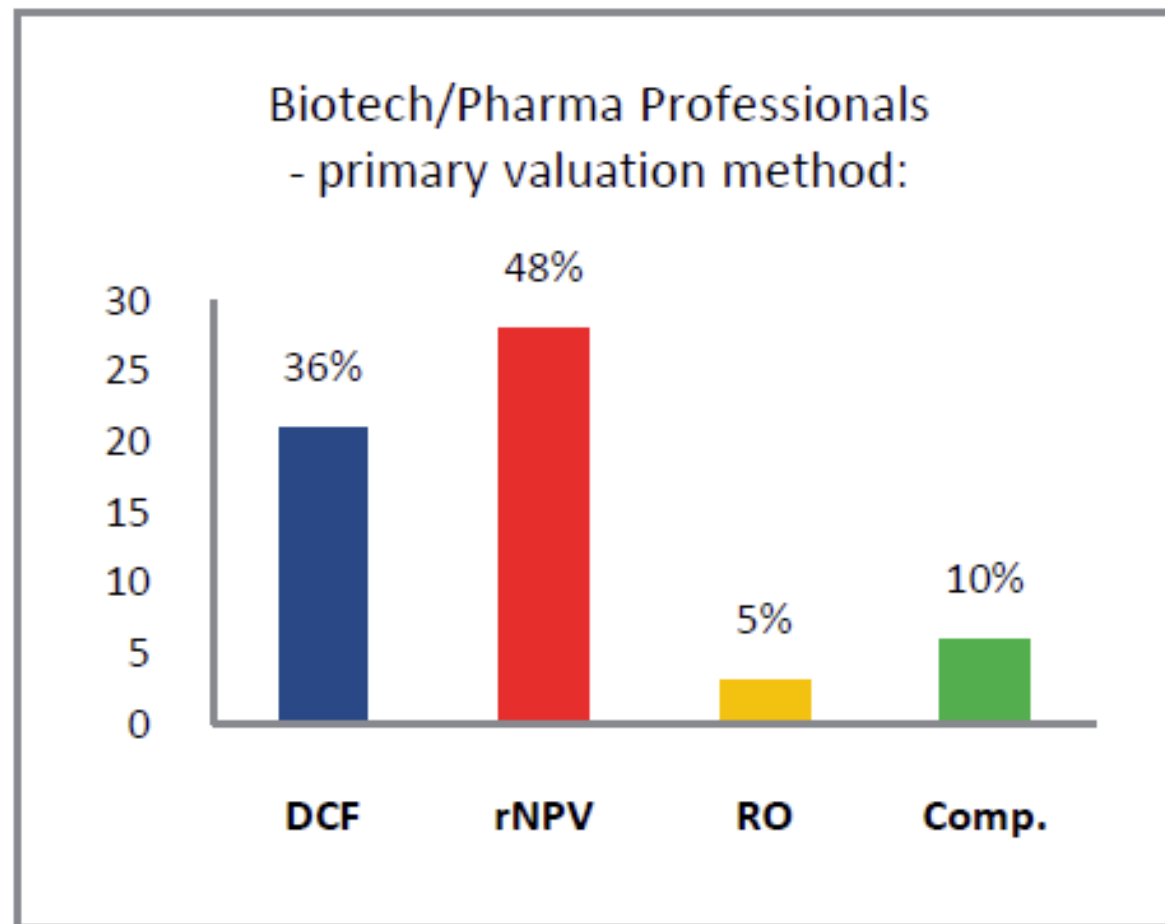
Used Most Often Across Areas

All respondents
- valutation methods used:

62% | 64% | | 58% | 17%

DCF | rNPV | RO | Comp. | Other

13%

Source: BIOSTRAT Biotech Consulting

Which Methods Do Pharmas Use Most?
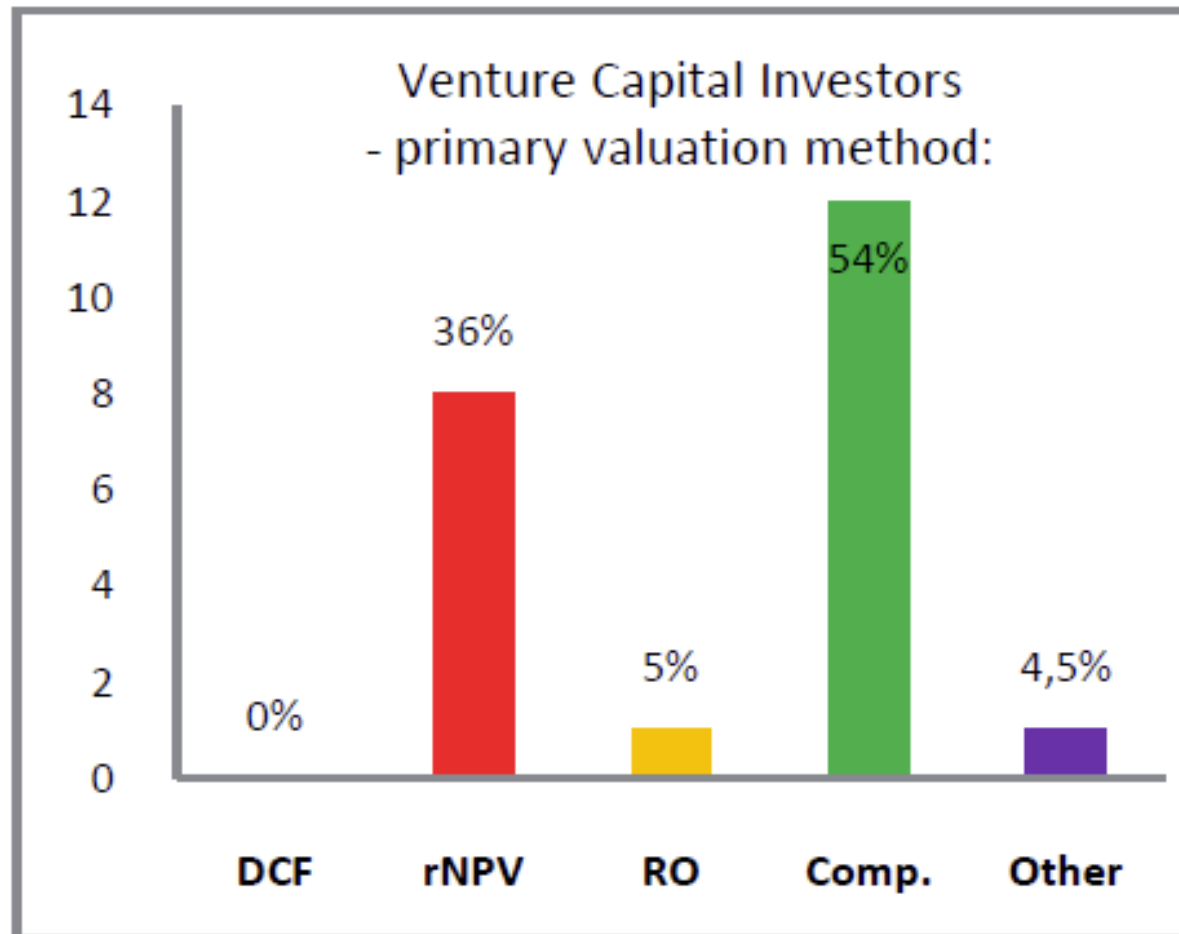
Used Most Often by Biotechs / Pharmas

Source: BIOSTRAT Biotech Consulting

Which Methods Do VCs Use Most?

Used Most Often by VCs

Venture Capital Investors
- primary valuation method:

DCF 0% · rNPV 36% · RO 5% · Comp. 54% · Other 4,5%

Know With Whom You're Speaking

- **VCs**
  - Fewer resources and time compared to pharma
  - Potentially different calculating framework (i.e., what do I think my likely exit is based on 4 other companies in this space, so therefore what pre-money valuation will I give in order to achieve a 10x return?)
  - **But a good analysis may give them confidence in the management team and allow them to consider a higher than otherwise valuation**

- **Pharma**
  - Have the resources to do full epi builds and downstream operations matter to them
  - **A good analysis allows you to justify better deal terms**

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Let's start with a few terms

- **Pre-money Value**: value at which company raises new round of capital
  - value is PRIOR to receiving new funding

- **Post-money Value**: Pre-money Value + amount of capital raised
  - Value is AFTER receiving new funding
  - Example: Biotech A has a pre-money value of $100 and raises $50; post-money value is $100 + $50 = $150
  - Note: "**New Money**" (investors putting in $50) now owns 33% of the company ($50/$150)

- **Exit Value**: what can I sell this company for in 3-7 years?

Let's start with the concept of DILUTION

- ■ What is dilution?
  - – Dilution is a reduction in the ownership percentage of a share of stock caused by the issuance of new stock.
  - – Dilution can also occur when holders of stock options (such as company employees) or holders of other optionable securities exercise their options.
  - – When the number of shares outstanding increases, each existing stockholder will own a smaller, or diluted, percentage of the company, making each share less valuable.
- • In the previous example, existing shareholders were diluted from 100% to 67%

May hay while the sun shines

- ▪ What does this mean?
  - ▪ Raise money while you can
  - ▪ In general, DO NOT worry about dilution
  - ▪ Small share of a big pie is worth a lot more than a large share of **0**

"Up rounds exceeded down rounds 67% to 25%, with 8% flat." (Fenwick & West SV VC Survey)

- What does this mean?
  - Up round: Company raised a round of financing at a higher valuation than previously
  - Flat: same valuation
  - Down round: lower valuation

- How is the valuation determined?
  - Priced at what market (i.e., new investors) will bear
  - Essentially, an illusory number based on group consensus

"Up rounds exceeded down rounds 67% to 25%, with 8% flat." (Fenwick & West SV VC Survey)

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	Flat Round	Up Round	Down Round
(a) Prior Post-money Value	$100	$100	$100
(b) Number of shares	100	100	100
(c) Prior $/share (a/b)	$1	$1	$1
(d) New Pre-money Value	**$100***	**$150****	**$50****
(e) Amount Raised	$50	$50	$50
(f) New Post-money (d+e)	$150	$200	$100
(g) Number of shares	150	150	150
(h) New $/share (f/g)	**$1**	**$1.33**	**$0.67**

* "Your company hasn't increased in value since the last time you raised money."
** "Your company has increased in value since the last time you raised money."
*** "Your company has lost value since the last time you raised money."

How does an investor (VC) value an early stage company?

- Investor starts with expected Exit Value in 3-7 years
  - "What have similar companies sold for recently?"
- Then determines what post-money value would give them a 5-10x return on their money
- Example
  - Biopharm B is raising $10M, which gets its lead asset through Phase IIa (POC); Biopharm B then wants to sell the asset
  - VC X believes similar assets at that future stage and for that indication have sold for $200M
  - VC X wants a 10x return on their money, so they would want their shares valued based on $200M / 10x = $20M post-money valuation
  - Since post-money value is based on pre-money + amount raised, pre-money = $20M - $10M = $10M pre-money value

Convertible Debt:
For the really early stage investors

- **Issue:** you want to raise money from friends and family
  - BUT: they (and you) have no idea how to fairly value your company to determine at what pre-money value they should buy equity
- **Solution:** convertible debt (also called convertible notes)
  - A financing vehicle that allows startups to raise money while delaying valuation until the company is more mature.
  - Though technically debt, convertible notes convert to equity at a later date, usually a subsequent round of funding.
  - Investors who agree to convertible notes generally get warrants or a discount as a reward for putting their money in at the earliest, riskiest stages of the business.

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Exit Timing

- Timing mismatch between VCs and life science companies
  - VCs are required to return capital within 10 years of start of fund, and usually 5-7 years from investment
  - Companies navigate significant R&D and regulatory challenges which can take more than 10 years

Plan Exit from the Outset

- Take the perspective of the investor
    - Are you addressing a reimbursable unmet need?
    - What milestones provide an inflection point that allow either additional funding, a partial exit (e.g., licensing) or sale?
    - How much money and time do you need to get there?
    - What is the probability of success of reaching these points?
- For therapeutics companies, milestones are often preclin or clinical POC
- For medtech, Dx and digital health companies, it's commercialization or break-even (i.e., no longer burning cash)
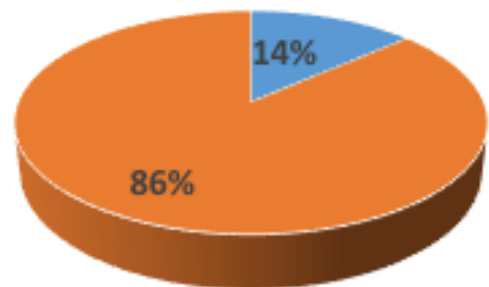
Licensing 101

- Think of total product value (based on risk-adjusted net present value of cash flows) as a pie
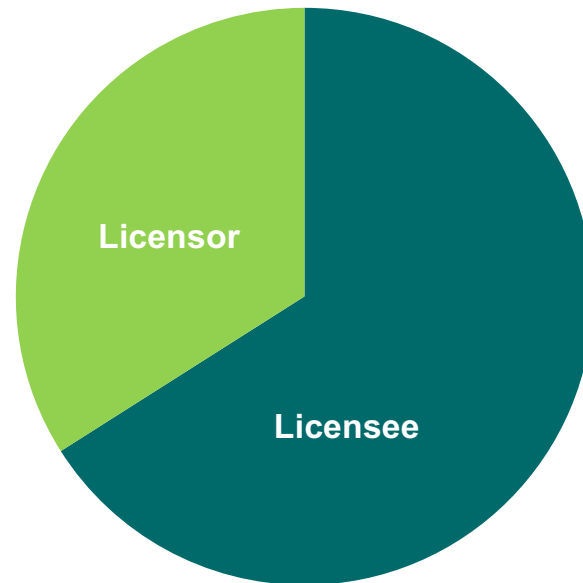
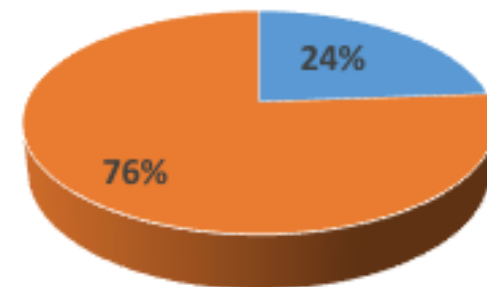- Pie gets split between the licensor and the licensee in the form of deal terms

Some thoughts on deal structuring

Share of Sum of Cash Flow Given Success

- 14% Out-licensor
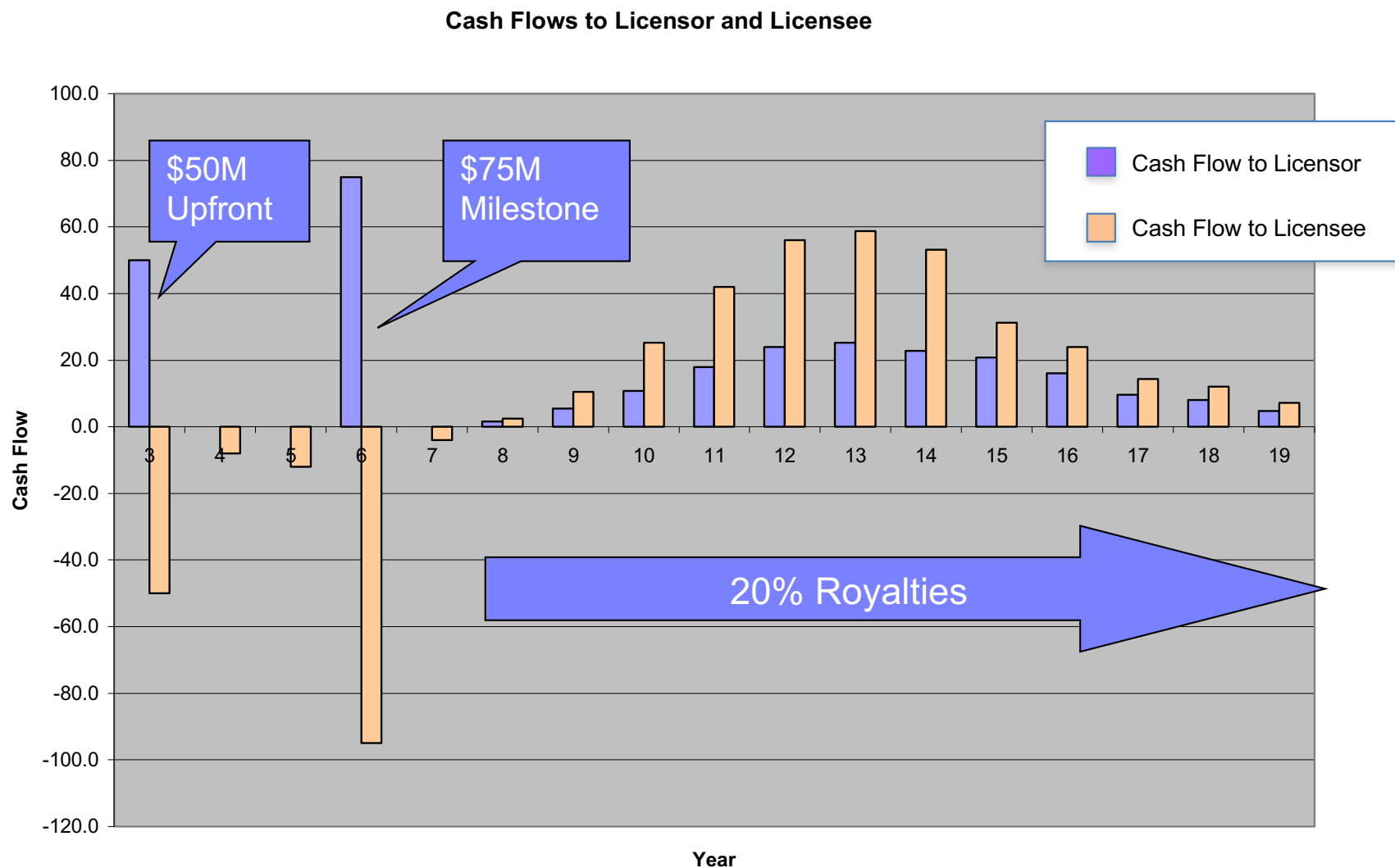- 86% In-licensor

Share of eNPV

- 24% Out-licensor
- 76% In-licensor

Why does the out-licensor have a larger share of the eNPV than the sum of cash flow given success?
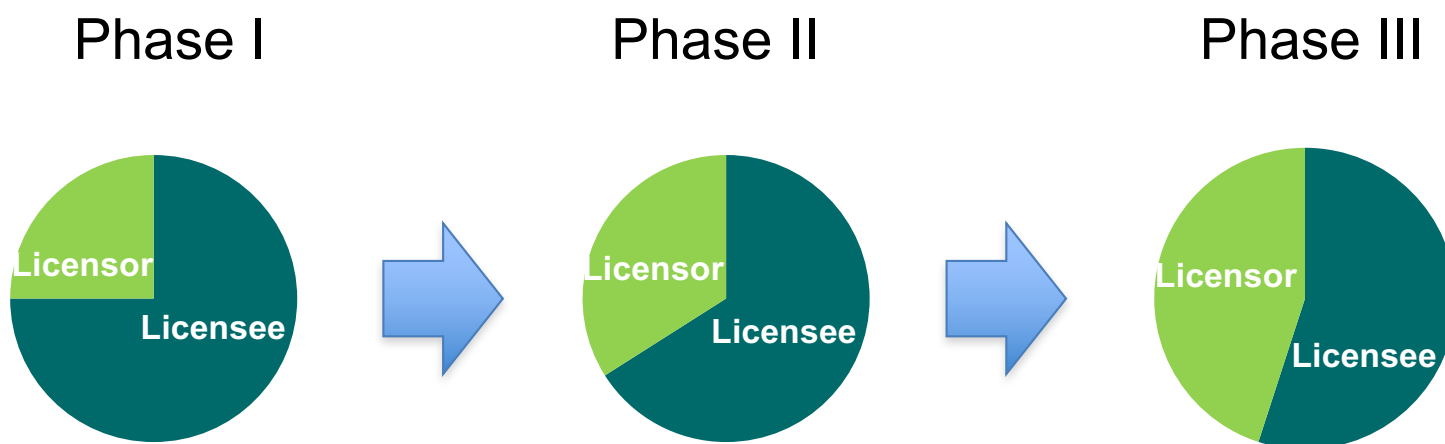
Expected Cash Flows Reflect Licensing Terms

Cash Flows to Licensor and Licensee

As a product moves forward in development…

…share to licensor increases.

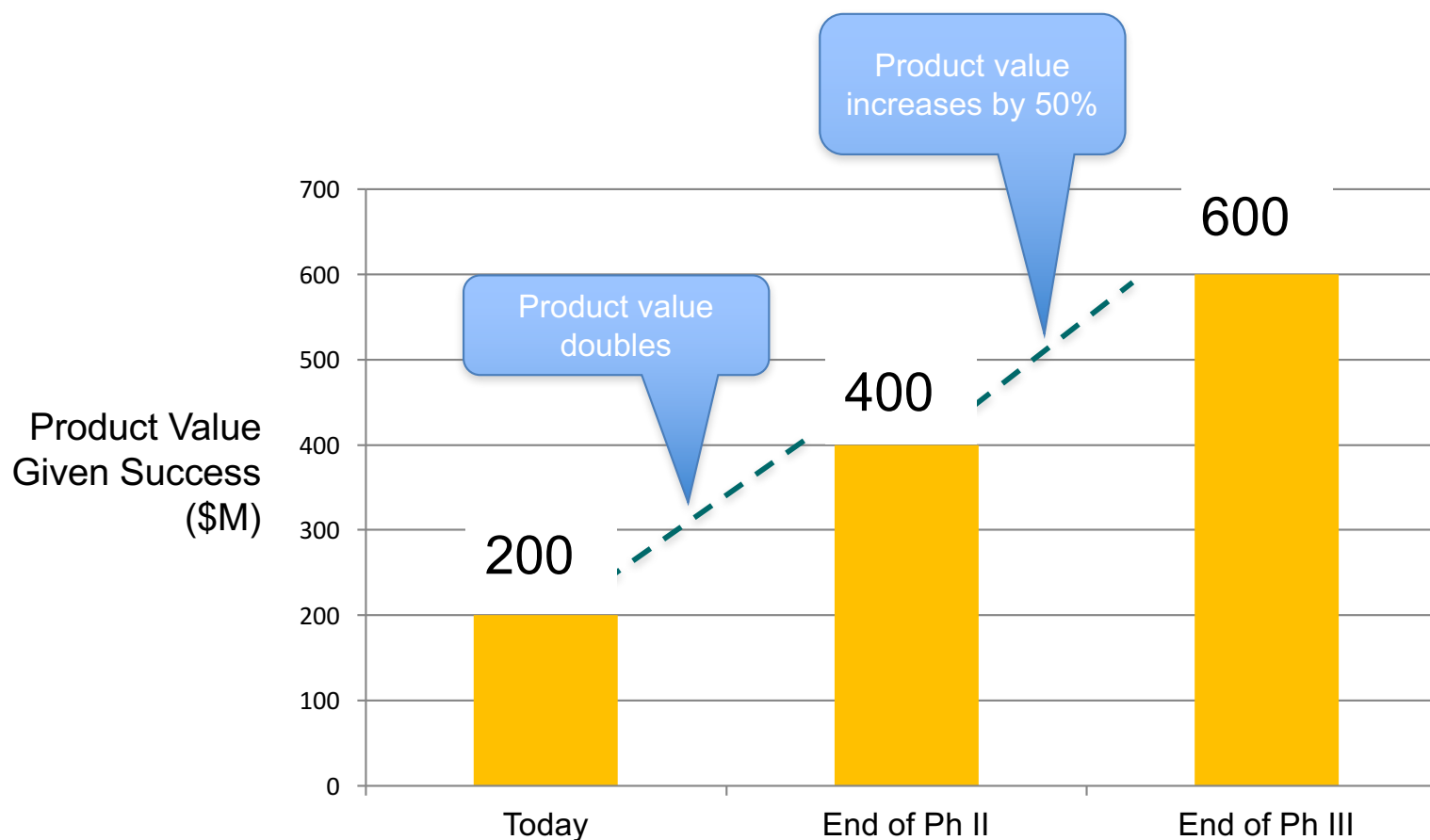| Phase I		Phase II		Phase III
Licensor / Licensee	→	Licensor / Licensee	→	Licensor / Licensee

Why? For a variety of reasons, but primarily
- Human nature: people and companies pay more for less risk
- 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

Key implication: product value increases substantially from a successful trial...
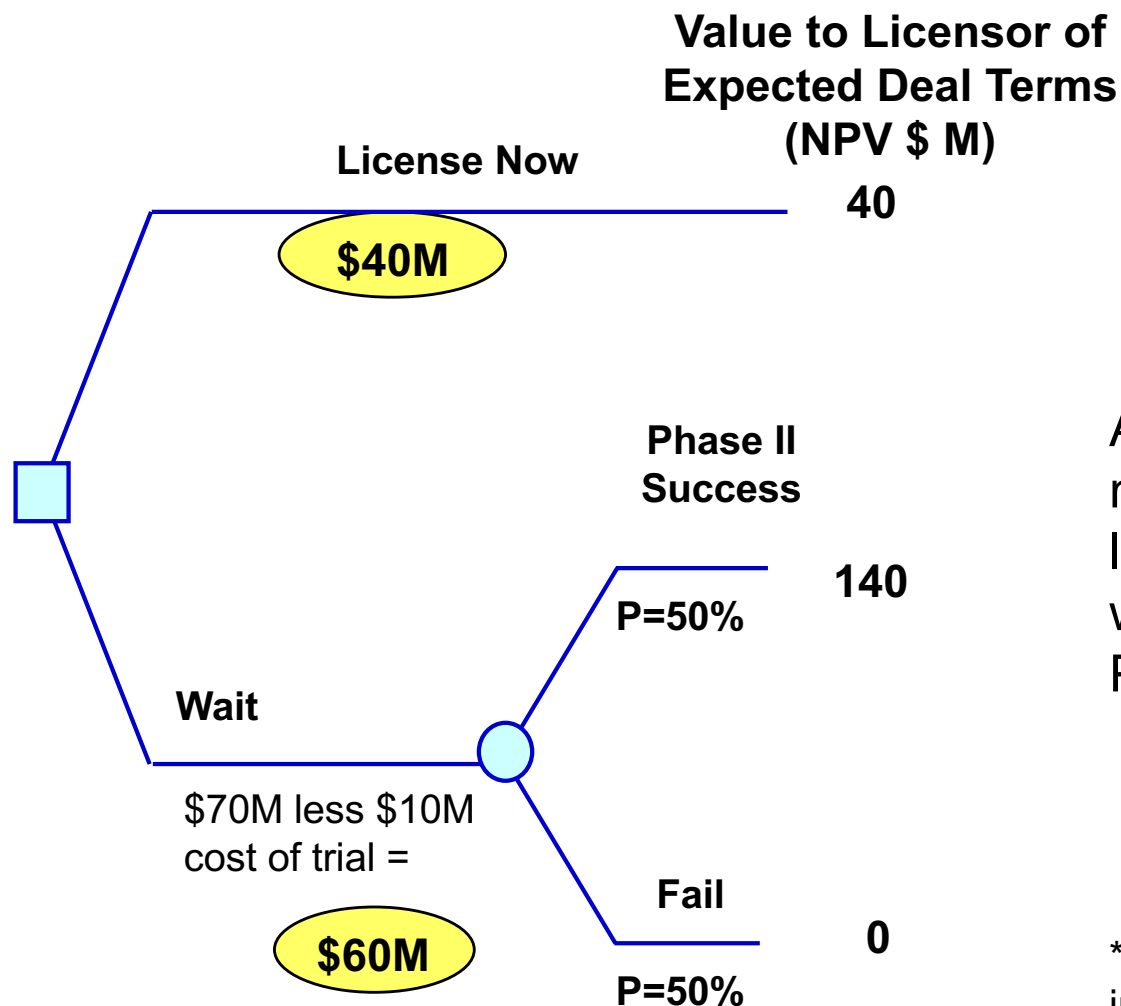
... But value to licensor increases by even more
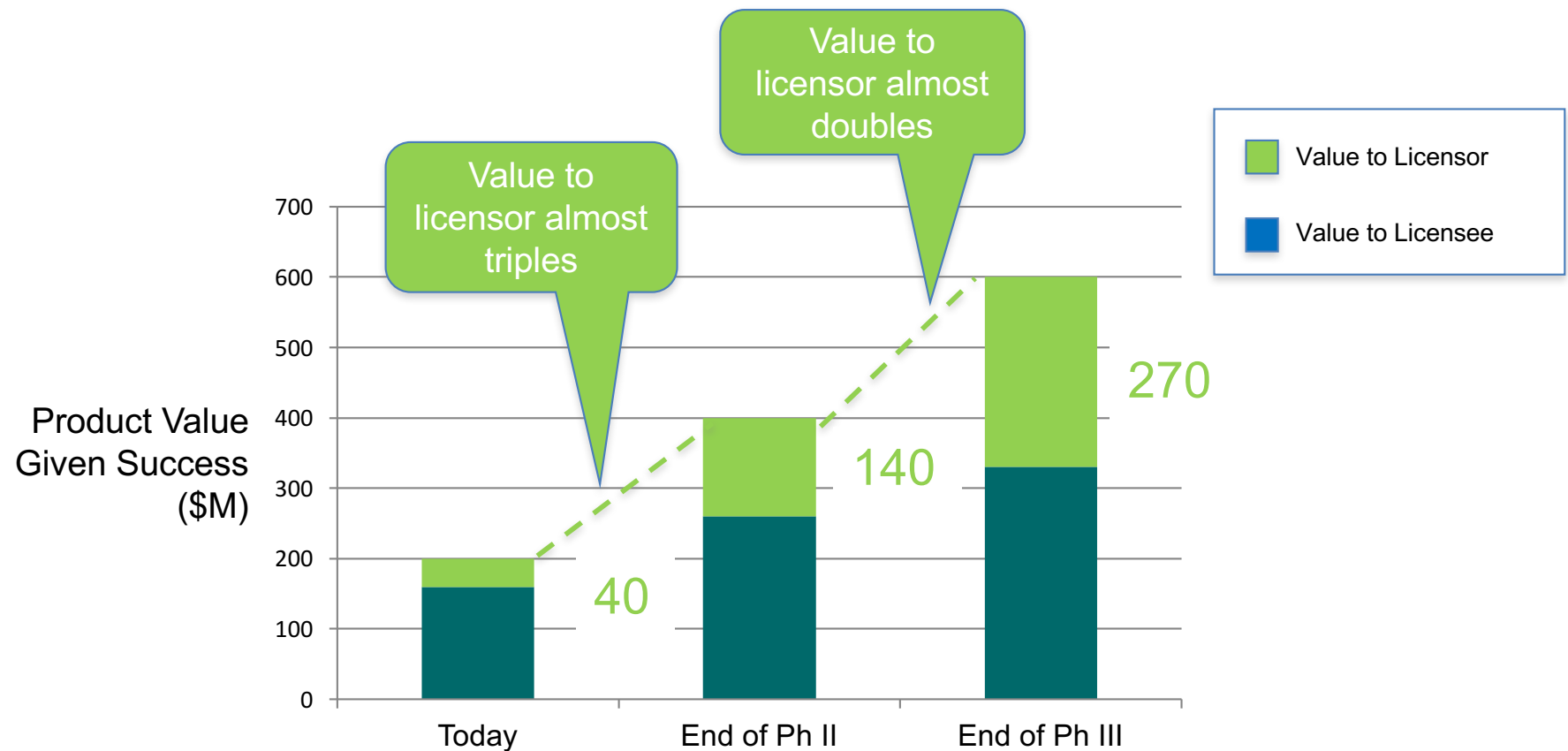
Application: License Now or Wait? (I)

- Assumptions
  - Phase II asset
  - 50% of success to get to Phase III
  - Phase II trial cost is $10M
  - License terms today: $40M
  - License terms given successful Phase II: $140M

Application: License Now or Wait? (II)

Value to Licensor of Expected Deal Terms (NPV $ M)

License Now

40

$40M

Phase II Success

140

P=50%

Wait

$70M less $10M cost of trial =

$60M

Fail

0

P=50%

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

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

Case Study: Licensing Transaction (I)

- Situation
  - Microcap public company had lead Ph III product for opioid addiction

- Challenge
  - This was a difficult story to sell
  - Heads of CNS BD in most pharma had no idea how widespread the addiction issue was and addiction generally was an unfavored TA
  - Heads of CNS at the time thought the highest selling product in the space was doing $60-80M, when in fact it was doing >$1B

Case Study: Licensing Transaction (II)

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- Strategy
  - Company market cap was so far below our view of the product's true value that our strategy was a full, upfront disclosure of our valuation analysis
  - We developed the story around the program to drive interest and value
  - Large part of this story was a deep dive into the reasoning behind the revenue forecast and commercialization expenses
  - Focus on IRR to partner given assumptions both sides can agree on

- Result
  - Had board instead sold company, it would likely have received a premium of 20-40% on a market cap of <$60M
  - Had it raised money, shareholders would have taken a significant dilution hit
  - Biobucks for the partnership deal struck was $305M partnership and, more importantly, eNPV to company shareholders was multiples of the expected acquisition price
  - eIRR to partner was >30%

Win-Win Structures Get Deals Done

Summary

- Valuation gives you negotiating leverage and improves decision making

- Entrepreneurs need to build companies from the perspective of the potential investors and partners

- Plan for your exit from the beginning