Technology Licensing Masterclass

Pune, India
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Dr. Ashley J. Stevens
President

FOCUS IP GROUP, LLC

TechEx.in Tech Transfer Hub

VENTURE CENTER

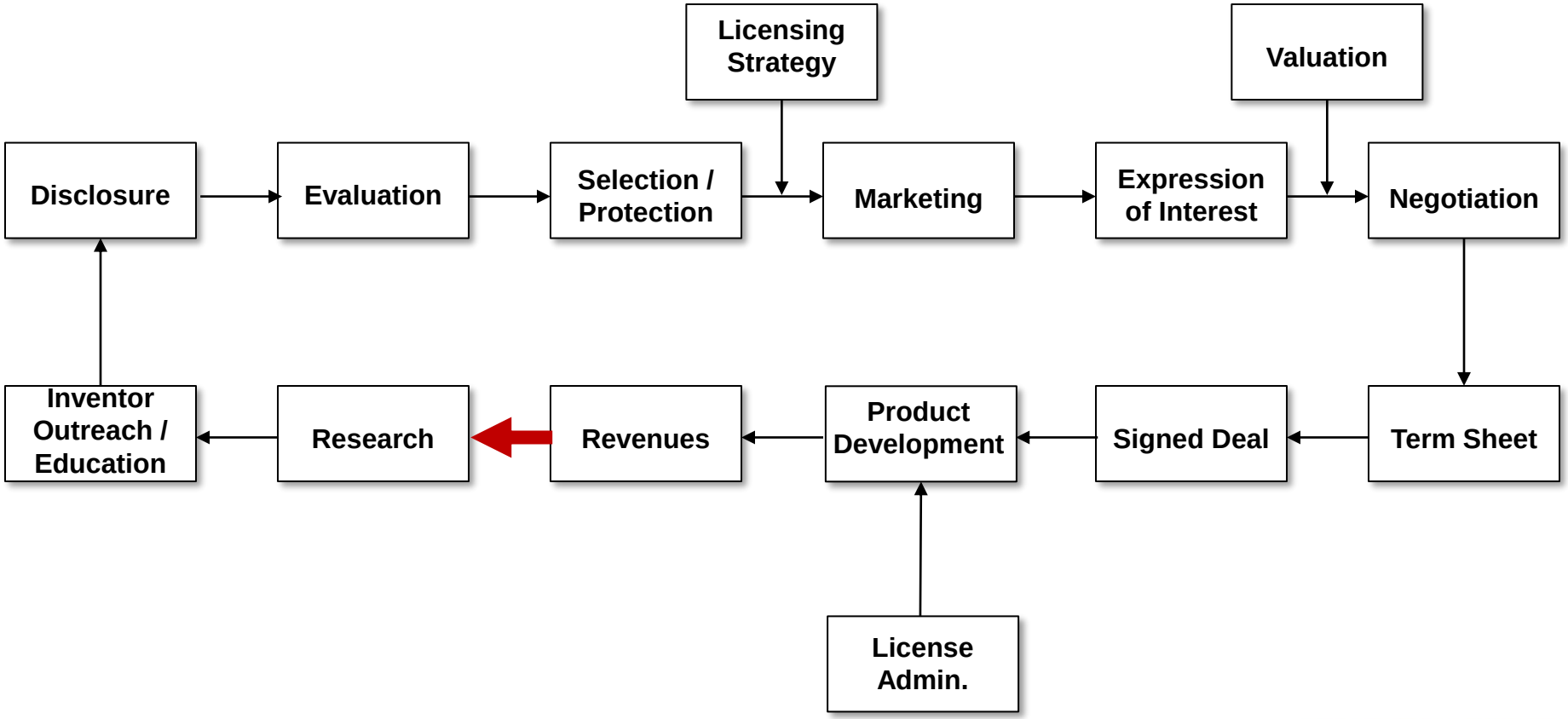
With thanks to:

Agenda

- **Monday February 5**
  - Introduction and setting the context of the workshop
  - Understanding technology licensing and how it works in practice
    - Tea / coffee
  - Technology assessment: The First Look Report
    - Lunch and tour
  - Anatomy of a licensing agreement and structuring of deals
    - Tea / coffee
  - Socially responsible licensing of drugs, vaccines and devices
- **Tuesday February 6**
  - Technology valuation
    - Illustration of how financial terms of a license can be estimated
  - Spinout creation
  - Art of the Cap table

Session 1
Understanding Technology Licensing and How it Works in practice

The Technology Transfer Process and Cycle



What Is a License?

- Academic institutions don't develop and sell products
  - Not in our mission
- We need to find a company to take an invention with promise and develop it
  - An existing company
    - Large
    - Small
  - A new company
    - Explicitly set up to develop the technology
      - A "start-up"
        - Aka a "spin-out"
- We then transfer the rights to them

Transferring the Rights

- Two ways we can do this:
  - We can assign the rights
    - Aka “sell”
  - We can license the rights
    - Aka “Rent”

What's the Difference?

You Buy a Place

- It's yours
  - Forever
  - Previous owner has no further rights
- The problems are yours
- You've paid upfront
  - But you got a mortgage and have on-going payments
- You can decide what to do with it:
  - Live in it
  - Rent it out
  - Rent out part of it
  - Sell it
  - Demolish it and build something bigger

You Rent a Place

- You have the right to live there
  - For the duration of the lease
    - And as long as you pay the rent
    - And as long as you obey any other rules the landlord imposes
      - Noise
      - Cut the grass
      - Take out the trash
      - Etc.
- The landlord fixes the problems
- The landlord still has rights
  - Owns it
  - Can decide whether to renew the lease
  - Can inspect periodically
    - To ensure you're obeying the rules

You Rent a Place from Airbnb

- You rent just a room
  - License part of the rights
    - Field of use
    - Territory

You Live in your Parents' Basement

- Failure to launch!

Tech Transfer Practice

- We license (rent)
  - Not assign (sell)
- In the U.S., the law doesn't let us assign if the research was federally funded
  - Without the permission of the funding agency
    - And they just won't give permission
      - They feel that an exclusive license gives the company all the control over the IP they need to successfully commercialize it
        - *"If Google can get started with an exclusive license from Stanford……"*
- About 50% of academic patent applications live in the university's basement
  - Can't license them

Why License not Assign?

- It's about failure, not success
- If the licensee fails to successfully develop our technology into a product
  - We want to get the technology back
  - To find someone else to develop it
- Much easier to get it back if you still own the technology
  - Give the licensee notice of termination of the license

But WHY does someone license something?

- Because they can't or won't develop a technology
  - University — Not part of the mission
  - Small company — Inadequate resources to take to market
  - Invention may not be sufficient to market a product
    - Platform technology – needs additional inventions to productize
- Do a deal whereby someone else bears the majority of the financial risk going forward
  - And receives the majority of the reward
  - The inventor / licensor receives part of the reward

In other words

- 5% (or 10% or 25%) of something is worth more than 100% of nothing

or even

- 5% (or 10% or 25%) of a big pie is worth more than 100% of a small pie

Types of Licenses

In-Licensing

- Acquiring the right to develop and sell a product
  - Enabling license – patents + know-how
  - Freedom to operate – route through toll gates erected by blocking patents

Out-Licensing

- Granting rights to intellectual property to others
  - Enabling license – giving up a product to someone with more resources
  - Freedom to operate – extracting value from a platform technology

Cross-Licensing

- Trading IP rights
  - Mutual elimination of road blocks
  - Competitive or non-competitive products

Types of Licenses

Enabling (Carrot)

- Includes know-how; often a collaboration
- Done at an early stage
- Patents probably still pending

Freedom to operate (Stick / Assertion)

- Naked
- Close to product launch
- Patents issued

Cross Licensing

- Two parties grant each other licenses to their patents
  - Fighting to a draw
  - Strengthens both versus the competition
- Can be royalty bearing or royalty free
  - Offsetting
  - Generally at concessionary rates

ensing

Sony, Samsung Will Share Bulk Of Their Patents

By Phred Dvorak
And Evan Ramstad

TOKYO—**Sony** Corp. and **Samsung Electronics** Co. said they agreed to share the bulk of their patents, in an unusual move that shows how changes in the electronics industry are pushing some rivals into closer cooperation.

The two giant electronics companies signed a cross-licensing agreement—or agreement to use each others' patents free of charge or for a discounted fee—that covers all technologies the companies deem basic, or roughly 90% of their vast patent holdings. In the U.S. alone, Sony, of Japan, holds about 13,000 patents while Samsung, of South Korea, holds about 11,000.

The companies also agreed on specific technologies, such as some relating to Sony's PlayStation videogames or Samsung's home networking, that each considers vital to its competitive strategies, and therefore out of bounds. They also kept to themselves some important technologies in the growing market for flat-screen television sets.

The agreement, which lasts until 2008, lets two of the world's biggest electronics makers develop products in an increasingly crowded market without worrying about butting heads—even as rivals are bogged down in litigation. It wasn't clear if the pact will pressure other companies to make similar moves.

Toshiba Corp. of Japan last month sued **Hynix Semiconductor** Inc., of South Korea, over memory-chip technology, while **Matsushita Electric Industrial** Co., of Japan, and South Korea's **LG Electronics** Inc. are embroiled in a plasma-patent dispute so fierce that they have managed to get each others' plasma panels banned from their home markets.

The Sony agreement with Samsung is an attempt to head off that kind of discord, according to Yoshihide Nakamura, Sony's senior vice president in charge of intellectual property. A Samsung spokeswoman said Samsung executives weren't available to comment.

In the U.S., most cross-licensing agreements don't raise antitrust problems as companies don't say they will be collaborating on product plans or prices. As a result, many companies with large patent portfolios routinely seeks cross-licensing accords, even with competitors.

December, 2004

Newer Companies

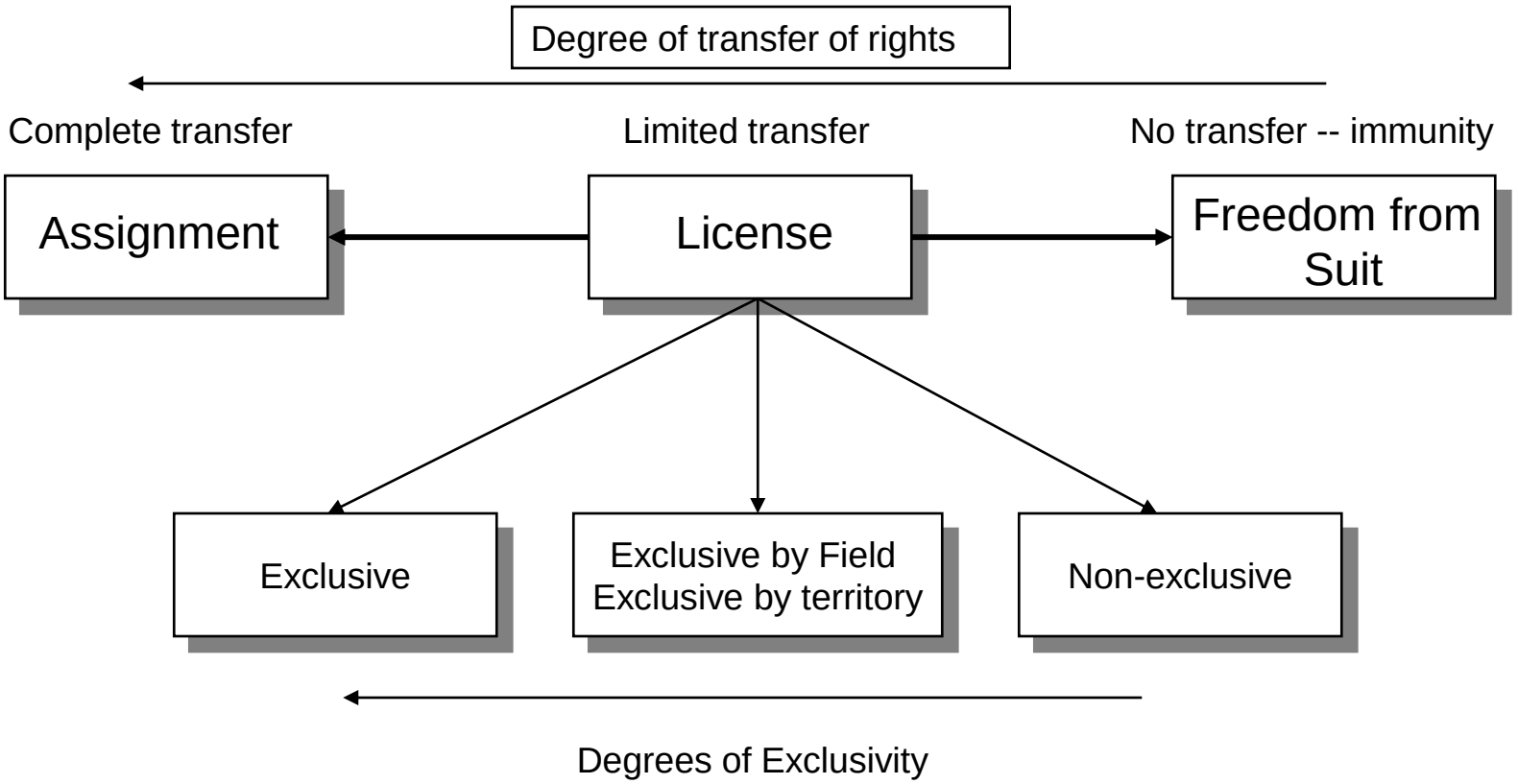
- Acquiring patent portfolios for defensive purposes
  - e.g., Facebook
    - Was third social networking site; late to the party
      - Friendster's first patent filed 2003 vs Facebook in 2007
    - Acquired ~1,500 patents from others

Seller	No. of Patents	Price ($mm)	Price/ patent	Date	Comments
IBM	750			3/22/2012	For Android; software, networking
Microsoft	650	$550	$846,154	4/23/2012	Majority of portfolio acquired from AOL;
Friendster/MOL	18	$40	$2,222,222	5/1/2010	Social networking
IPG (Philips)	11				
Walker Digital	9				
Hewlett Packard	9				
C. Cheah & A.Tuzhilin	5				
British Telecom	3				
Divan Industries	1				
Applied Industries	1				

    - Sued by Yahoo over 10 patents
    - Settled
      - Cross license, strategic partnership

License Grant

Different Degrees of Rights Can be Granted



Questions

Tea / Coffee

Session 2
First Look Technology Assessment

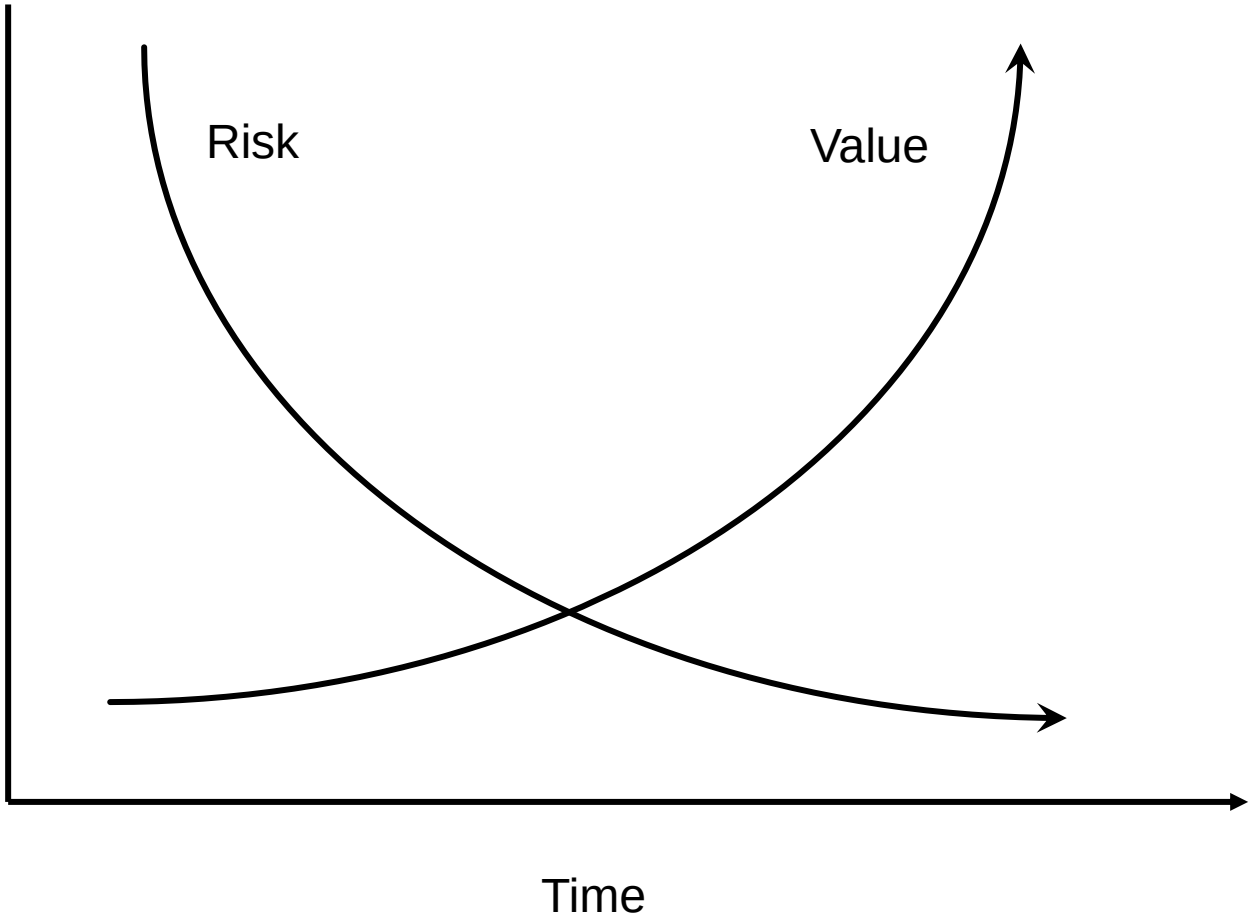
Technology Commercialization

- Academic inventions are embryonic
  - The technology is unproven
  - The market demand is unknown
- Commercialization is all about risk reduction
  - The Technology Evaluation is the first round of risk reduction
  - There will be successive rounds of risk assessment / reduction
    - Generally tied to:
      - License transactions; or
      - Financing

Technology Assessment

- The foundation of a tech transfer office
- All experienced practitioners have some form of Technology Assessment
  - Mine is the “First Look Technology Assessment”
    - G-TEC is a week of doing a First Look Technology Assessment
    - My system derived from Brett Cornwall’s “Quick Look Technology Assessment”
      - IC^2 at the University of Texas Austin
  - Dick Cahoon’s is the Ten Point Technology Scoring System (TPTST)

Value vs. Risk



First Look Technology Assessment Template

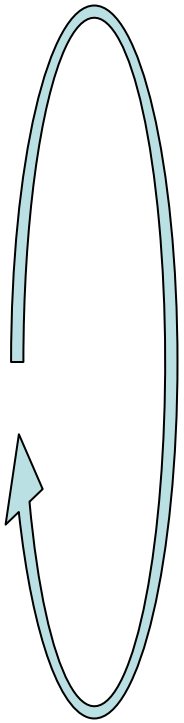
- A critical step in the technology transfer process
- Need to do it upfront
  - Otherwise you make bad decisions
    - File on most disclosures
      - No good reason to explain to faculty why you're not going to go ahead
    - Kicks the can down the road
      - If the technology's no good, you're going to have to face up to it eventually
        - Faculty will be more disappointed if they've put a lot of work into the patenting effort

First Look Technology Assessment Template

- The process
- Methodology
- Report format
- Ranking methodology
- Outcomes
- Experiences

Assessment Outline

- Technology Description
- Value Proposition
- Product Vision
- Potential Markets
- Market Interest
- Competing Technologies and Competitors
- Barriers to Market Entry
- Development Status of Technology
- Intellectual Property Status
- Pathway to Market



In real life, this is a never ending process

First Look Technology Assessment Template

- Important to let faculty review the document and recommendations
  - Before it's finalized and issued
    - "Have I missed something or misunderstood something?"
  - Perhaps you have and you need to do more work
  - But if they can't argue with your data or analysis
    - They now share ownership with you

First Look Technology Assessment Template

- It's all about trying to work out if the technology will work in the real world
  - And if anyone will care
- Faculty will have thought through the science
  - What they propose will be scientifically / technically feasible
- But will it be practically feasible?
  - Is there a market?
  - Does the invention fill unmet market needs?
  - Are we going to get a patent or other protection?
  - What's the competition?
  - Will it work on a large scale?
    - Can it be made economically?
  - What are the regulatory barriers to market entry?
  - What's the commercial pathway to market?

Methodology

Step 1 – Obtain a complete description of the technology and how it translates into products and services

- Talk to inventor

Step 2 – Assess stage of development of technology and next steps

- Talk to inventor

Step 2 – Search for competing patents or prior art

- Talk to inventor

Step 3 – Identify potential markets and competing products

Step 4 – Secondary Research

- Identify end users, distributors and potential licensees

Step 5 – Primary Research

- Contact experts and companies

Step 6 – Write the report and fill holes if necessary

Step 7 – Prepare presentation

Discussions with the PI

- Your Objectives:
  - Establish a positive relationship with the inventor
    - Keep the door open for follow-up questions
  - Obtain the benefit of their thinking
    - They've been thinking about this for a long time
    - They know the market
  - Understand the science
    - What it can do
    - How it's superior
    - What are the competitive approaches
  - Their thoughts on the most attractive applications of the technology

Discussions with the PI

- Objectives (cont.)
  - Get their help on patent searching:
    - What are the key terms to search for?
    - What are other terms that capture those concepts?
  - What is the stage of development of the technology?
    - Their thoughts on where we go from here:
      - What are the key proof-of-principle experiments that need to be done?
      - How easy will it be to fund those experiments?

Discussions with the PI

- Be well prepared with specific questions, e.g.
  - What distinguishes it from prior art?
  - Needed development time/resources, etc.
  - What are the limitations? When doesn't it work?, etc.
- Start with a bullet point summary in your head, see if it changes
- Be ready to be surprised you've completely misunderstood!
- Don't take anything but the science at face value
- Be judicious with their time…

Report Content

1. Technology Description and Resulting Products
2. Potential Benefits
3. Potential Commercial Markets and Market Interest
4. Development Status of the Technology
5. Ease of scale-up
6. Technology Development Plan
7. Intellectual Property Status of the Technology
8. Competing Technologies and Competitors
9. Pathway to market
    1. Potential licensees
10. Barriers to Market Entry
11. Commercial Potential Rating
12. Recommendation

Evaluating Early Stage Technology

- It's all about visualizing the products the science leads to
- Scientists send us raw disclosures:
  - Detailed science
  - Light on technology
  - Hints of a product
  - Devoid of a value proposition
- Industry buys products:
  - User oriented
  - Need clear benefits
    - The Value Proposition
  - Must be competitive

Step #1: Focus on the underlying value of the science

- Understand the technology

  (Requires meeting with the inventor or graduate student to grasp the problem(s) the technology solves, what it does, how it does it etc…)

- …having an understanding of the technology will enable you to imagine what kinds of products can be created from it (sometimes different from inventor's vision) and to effectively communicate the value to others

Step # 2: Give the Customer a reason to buy

- Look at everything through the eyes of the Customer
- The most important decision is the decision to buy
- To a Customer, a product is a collection of need satisfying attributes

  hurting → buy pain killer
- **The challenge is to match the value of the science to the Customer's needs**
- The more closely aligned the need is to your technology, the stronger the **value proposition**

So, Who is the Customer?

- Different people in different markets
  - The person who **pays for your product/service**
  - The person who **uses your product/service**
  - The person who **recommends your product/service**
  - The person who **delivers your product/service**

Step #3: Communicate the Value Proposition

- Briefly describe how the technology works
  - What is the product?
- Focus on the unique scientific merits of the technology that distinguish it from what currently exists
  - What is the unmet need?
- Avoid getting into great detail and using scientific jargon
- Don't give away all the enabling details
- This analysis feeds into preparation of initial marketing materials

The Value Proposition

- Value = Benefits received / perceived by the Customer
- The Customer defines and evaluates Value

The Value Equation

- The Value Equation:

Value = Benefits – Costs

- How can you increase Value?

1. Description of Invention and Inventiveness

- Does the Invention Disclosure thoroughly and clearly describe the invention;
  - What it is and how it works?
- Are the inventive features clearly delineated and explained?
- Do the inventive features appear to be technically meaningful / significant?
  - Not simply a distinction without a difference
    - “Must Have” vs “Nice to Have”
- Are the superior performance features described clearly?
- Does it work?
  - As hoped?

Patent Due Diligence

- Two Levels of Analysis
  - Patentability
    - Us
    - Likelihood of getting our patent issued
      - Prior Art
      - Obviousness
  - Freedom to Operate
    - Them
    - Dominating patents
      - Will need a license to them to be able to practice our patent

FLTA

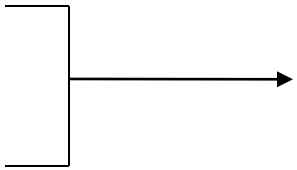
FLVA

Prior Art Searching

- One of the first steps in evaluating a technology
- Are we going to be able to get the right sort of patent to protect the products we envision?

Criteria for patentability

- Novelty
- Utility
- Non-obviousness



Prior art search

Mechanics of IP searching

- Search engines
- Search terms
- Search strategies

Types of Searches

- Patent Searches
  - USPTO
  - WIPO
  - EPO
- Non-Patent Searches
  - "Literature"

What tools are used to search patents?

Finding Patents

- **USPTO** – www.uspto.gov/patft/index.html
- **WIPO** – www.wipo.int/pctdb/en/search-adv.jsp
- **European Patent Office** – worldwide.espacenet.com/
- **Google Patents** – www.google.com/patents?hl=en
- **Prior Smart –** www.priorsmart.com
- **Patentlens** – www.patentlens.net
- **FreePatentsOnline -- www.freepatentsonline.com**

Search Terms: Work with the Inventors!

- Use alternative terms
  - e.g. “steerable needle”=“manipulator”
  - “nanowires” = “thin channels”
- Names of competitor academic labs
  - PIs have best information (but still may not be enough)
- Names of competitor companies
  - PIs, patent assignees, licensors

2. Potential Value of Intellectual Property

- Is it patentable *vis-a-vis* the prior art
  - Is there an International Search Report
    - Are there “X” references?
- Is there an issued or pending patent on the invention?
- Do the claims effectively cover the invention?
- Will the claims be reasonably enforceable?
- In which countries do potential or existing patent claims exist
  - Are these relevant to the market for the invention?
    - Local – Utility model adequate
    - Global – Was PCT timely filed

2. Potential Value of Intellectual Property

- Are other types of IP possible or existing?
  - Trademark
  - Copyright
  - Plant Breeders' Right
  - Trade Secret
  - Traditional Knowledge
- Is there potential or existing "bioproperty" that may have value in commercialization of the technology?
- What is the Property Control Position ("PCP")

3. Market Relevance

- Does the invention solve a problem that is economically meaningful?
- Is the problem widespread and significant or localized and trivial?
- Is there a definable market for the problem solved?
- How does the technology compare to existing solutions to the problem?
- What feedback have you got from the market on their interest in the technology?

A Two Step Process

- Secondary research ➔ Primary research
  - Secondary research = OPR (Other peoples' research)
  - Primary research = MR (My research)

Stay skeptical

- Assume everything already exists
- First search for things that destroy your opportunity, then search for things that support it.
  - A quick kill of a project early in the process is preferable to wasting time on a dead end.
  - People (mistakenly) tend to focus their attention on supporting evidence
  - Investors look for ways to say NO

Secondary Research Resources

- Google
- Business School Library
- Subscription Services
  - Frost & Sullivan

Healthcare

- Much easier than physical sciences/IT/Software
  - Need is more obvious
  - Addressable market size is easier to estimate
  - Range of possible products is usually constrained

Healthcare

But… horizons vary

- Drugs
  - Stage of development is earlier
  - Leads to far reaching assumptions about performance
- Devices
  - Returns are usually much lower than drugs
  - Therefore risk must be much lower
  - Translation: 510K, replace an existing therapy, has an established reimbursement code
- Diagnostics
  - Market is highly competitive (many solutions, many entry points…)
  - Incumbents require compelling data
  - Expectations on performance are much higher (clinical samples)

Physical Sciences & IT

- Many possible products
- Many possible markets
- Varying levels of competition
- Value chains not clearly defined
- Market data harder to identify

4. Market Size and Characteristics

- Is there one or more identifiable markets for the problem solved?
- How large are these markets?
  - The specific “addressable” market for our invention
- Are the markets characterized by:
  - Few large firms or
  - Many medium-small firms?
- Where in the value / supply chain will you fit?
  - Further downstream you can go, more of the value you capture
- Will these markets sufficiently value the problem solved?
- Does governmental regulation have a significant impact on the market for the new products / services?

5. Value Proposition / Potential for Reasonable Business Model

- Can at least one “value proposition” be described and substantiated for the invention, in at least one market application?

  Value Proposition = Quantitative Benefit – Quantifiable Cost

- Is the value proposition feasible?
- Can you identify at least one reasonable business model for the selected value proposition?
- Is this business model suitable for:
  - A disruptive / paradigm shift, or
  - A revolutionary, or
  - An incremental (large or small)

  innovation?

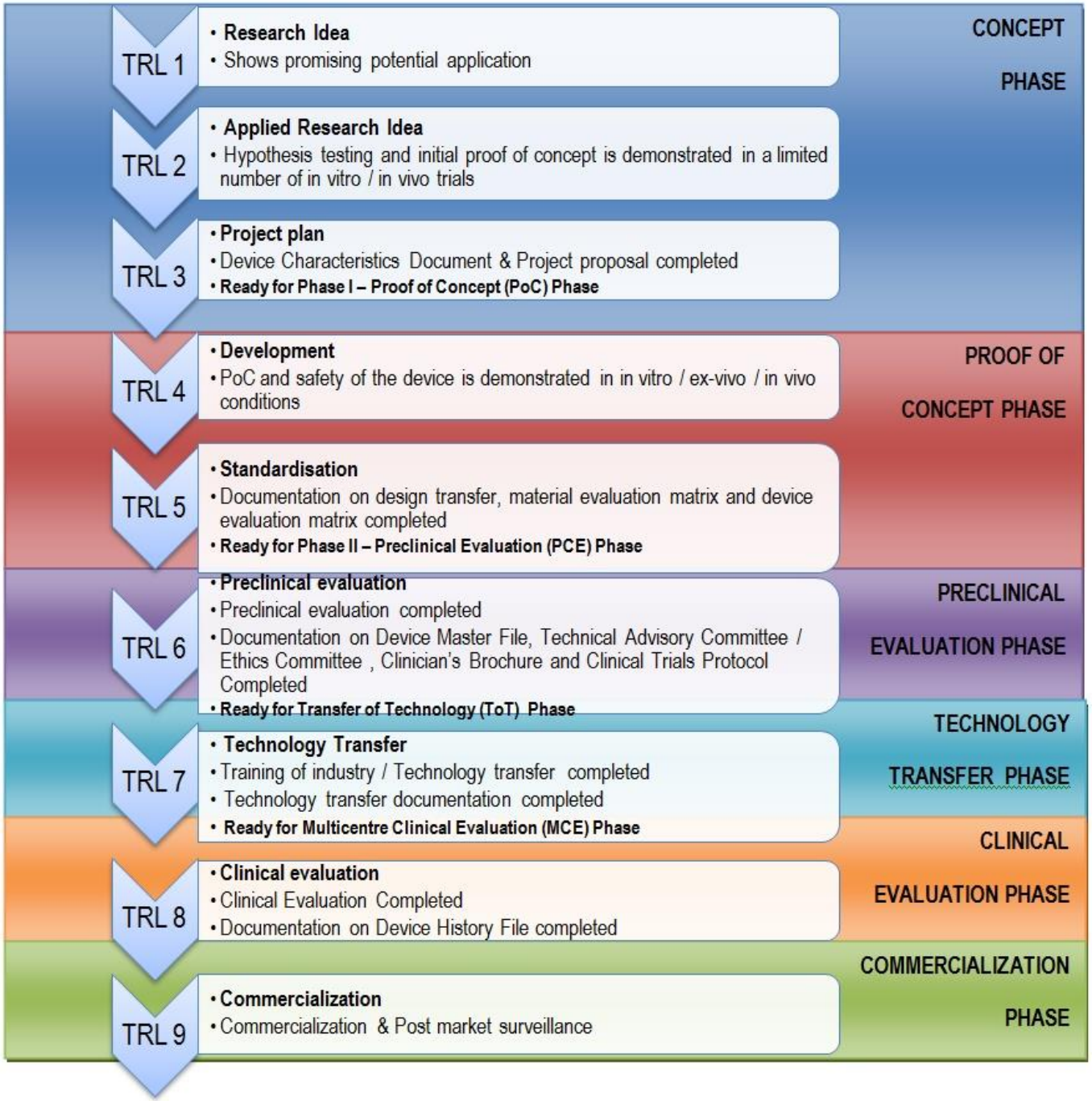
6. Potential for Significant Economic Value

- Does the combination of:
  - Value proposition,
  - Market size
  - Business model, and
  - Market characteristics

  establish the basis for significant economic value?
- Will the realization of that value require:
  - Very large
  - Large
  - Moderate, or
  - Small investment?
- Will the potential return justify the investment required?

7. Stage of Development /Technology Readiness Level

- What is the current stage of technical development of the invention:
  - Idea
  - Test-tube proof
  - Bench-test validation
  - Extensive testing
  - Pilot scale
  - Beta-test
  - In application, etc?
- Where is the invention on the Technology Readiness Level scale?
- What level of risk (that the technology will not work as expected / hoped) is the technology currently at?



r Modify

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Manufacturing Readiness Level (MRL)		
Phase	MRL	State of Development
Phase 3: Production Implementation	9	Full production process qualified for full range of parts and full metrics achieved
	8	Full production process qualified for full range of parts
	7	Capability and rate confirmed
Phase 2: Pre production	6	Process optimised for production rate on production equipment
	5	Basic capability demonstrated
Phase 1: Technology assessment and proving	4	Production validated in lab environment
	3	Experimental proof of concept completed
	2	Application and validity of concept validated or demonstrated
	1	Concept proposed with scientific validation

8. Getting from Here to There

Risk Reduction

- What are the next few steps needed to reduce the risk to where the technology is investable?
- Will those risk reduction steps be relatively easy or difficult?
  - In terms of time and money
- Will you be able to secure that proof-of-principle funding?
- Will the cost required to de-risk the technology be justified by the potential return on needed investment?

Scale-Up Feasibility

- Can the technology be cost-effectively scaled-up to a level of profitable manufacture or service delivery?

8. Getting from Here to There

Barriers to Entry

- What road blocks are there between this technology and market entry?
  - Long and hard regulatory path?
  - Market reluctance to adopt?
  - Reimbursement?
  - Entrenched players:
    - Need an overwhelming sales force?
    - Who would lose and how would they react?
  - *How many right things have to happen for your product to be bought?*

9. Support, Funding and Resources

- Are there resources readily available to further develop the invention:
  - Money
  - Staff
  - Facilities
- Is development funding readily available?
- Are there additional resources available to help develop the technology from its current stage to commercialization?
- Are there other pre-commercialization partners who can help with risk reduction?
  - Another academic partner who uses this technology?
  - A government lab or NGO?
    - Who'd self fund their activities because our technology addresses their mission

10. Existing or Potential for Private-sector Partnerships

- Is this technology going to be developed with an existing company or does it need a start-up?
- If an existing company, who are some potential partners?
  - Do relationships with any of these potential partners exist?
  - Are these partnerships closely linked to commercialization activity?
- If a start-up company, is there investment interest?

Scoring

- Score each category1-5
  - 1= Very Unfavorable
  - 2= Unfavorable
  - 3= Neutral
  - 4= Favorable
  - 5= Very Favorable
- Maximum possible 10 * 5 = 50

Technology Rating

Factor	Weight	Score (1-5)	Weighted Score
Market Potential	15%		
Market Maturity	15%		
Current Status of Technology	15%		
Proof of Concept/Prototyping	15%		
Ease of Scale-up	10%		
Competitors	15%		
Patents	15%		
Total			

Technology Rating

Factor	Weight	Score (1-5)	Weighted Score
Market Potential	15%	3	0.45
Market Maturity	15%	4	0.6
Current Status of Technology	15%	2	0.3
Proof of Concept/Prototyping	15%	4	0.6
Ease of Scale-up	10%	2	0.2
Competitors	15%	3	0.45
Patents	15%	4	0.6
Total	100%		3.2

Technology Rating

- Critically important to explain why each score is being awarded
  - This is where you show the inventor where the weaknesses are
    - Get his buy-in on why not to proceed
    - Show him where things could be improved
      - E.g., More reduction to practice / proof of concept
- Scores tend to come out in range ~2.0-3.0
  - Academic technologies are embryonic!
- Value of scoring to the TTO is to compare one technology with another
  - Prioritization of resources
  - History as a guide to the future

Outcomes

- Go >3.5
- Kill <2
- Conditional Go 2.5-3.5
  - Go if…..
- Conditional Kill 2-2.5
  - Kill unless…..

Case Studies

Experience at Boston University

- Junior licensing staff were responsible for managing disclosures
  - Responsible for initial assessment
  - Soon overwhelmed
    - ~100 disclosures per year
    - 2 Licensing Associates
- First mitigation step was to contract with Foresight Science and Technology
  - Did initial assessments for $750 per assessment with a minimum annual commitment
- Second mitigation step was to bring in-house
  - Train and use grad student Technology Analysts
    - First choice students who had taken my course
    - Second choice recruits via a one day training course on ~3rd or 4th Saturday of semester

Experience at Boston University

- Student Analyst concept developed at U. of Illinois Urbana-Champaign in 1990's
  - ~750 untouched invention disclosures
  - State appropriated $3 million to fix problem
    - All consulting companies approached said they couldn't evaluate 750 invention disclosures for $3 million
      - $4,000 / disclosure
    - One proposed teaching UIUC to evaluate them themselves
      - Developed protocol and training materials
  - Implemented and highly successful
    - Last Director joined as Student Analyst
      - Now Director at MIT

Experience at Boston University

- We found ~20 hours for a student to do an assessment
  - Grad student rate of $13.65 / hour ➔ ~$275 / assessment
    - 1/3rd Foresight price
      - And better
      - And kept data sources in-house
- Tended to hire:
  - Physical Sciences: Ph.D. students
  - Life Sciences: MBA's with a life sciences undergrad
- Workload 10 hours / week in semester
  - Full time in vacations
- Good for the students
  - Looked like meaningful commercial experience on their resumé's
  - Valuable for students who won't pursue an academic career
    - Which is the vast majority!

Experience at Forsyth Institute

- Founded in 1910 to improve the dental health of the poor children of Boston
  - Created the concept of the Dental Hygienist
- Now a small (~$25 million research budget) research institute rooted in oral health
  - Basic research
  - Clinical research
- Affiliated with Harvard Dental School
- Too small for a full time TTO
  - Has always supported faculty entrepreneurship
    - Paid for patent filings
  - No other administrative support for faculty

Experience at Forsyth Institute

- I have chaired Patent Committee since 2012
  - Executive Patent Committee
    - Decides what inventions to file on
- Were going to hire someone to market technologies
  - I talked about the BU student system
    - A Forsyth employee was taking my class in Fall 2011
      - M.Sc. level scientist working in a core facility
      - One of the best students
    - Wanted to get more involved with business side of innovation
    - Transferred to work for tech transfer 3 days per week
      - Stayed in core facility 2 days per week
    - First wrote a Tech Brief on every existing patent family

Experience at Forsyth Institute

- Next started writing a First Look Technology Assessment for each new invention disclosure received
  - ~1 per month
  - Writes truly outstanding assessments
- After 1 year, the most senior and also most entrepreneurial Forsyth scientist said at end of a Patent Committee meeting

  "You've transformed faculty's attitude to technology transfer. They used to think they were on their own; now they feel the Institute is really trying to help them.
- We took much better decisions
- Several faculty whose inventions we decided not to proceed with stayed engaged
  - Improved the inventions
  - Disclosed new inventions

Questions:

Lunch, Tour of Venture Center

Session 3
Anatomy of a License Agreement

Contractual Aspects

- When you license something to somebody, you're creating a relationship which, if successful, will last 20 years
- Relationships are unequal
  - Licensor has made their investment
    - Looking for a return on that investment
  - Licensee is taking on substantial risk
    - Financial
    - Opportunity cost

License Agreement Outline

- Recitals
- Definitions
- License Grant
- Fees, Royalties, & Payments
- Patent Prosecution & Infringement
- Obligations of the Parties
- Representations & Warranties
- Indemnification & Insurance
- Confidentiality & Publication
- Term & Termination
- Miscellaneous

Recitals

- The “WHEREAS” clauses
  - Establish the background to the current agreement
  - Establish the purpose and objectives of the parties
  - Non-Binding

Definitions

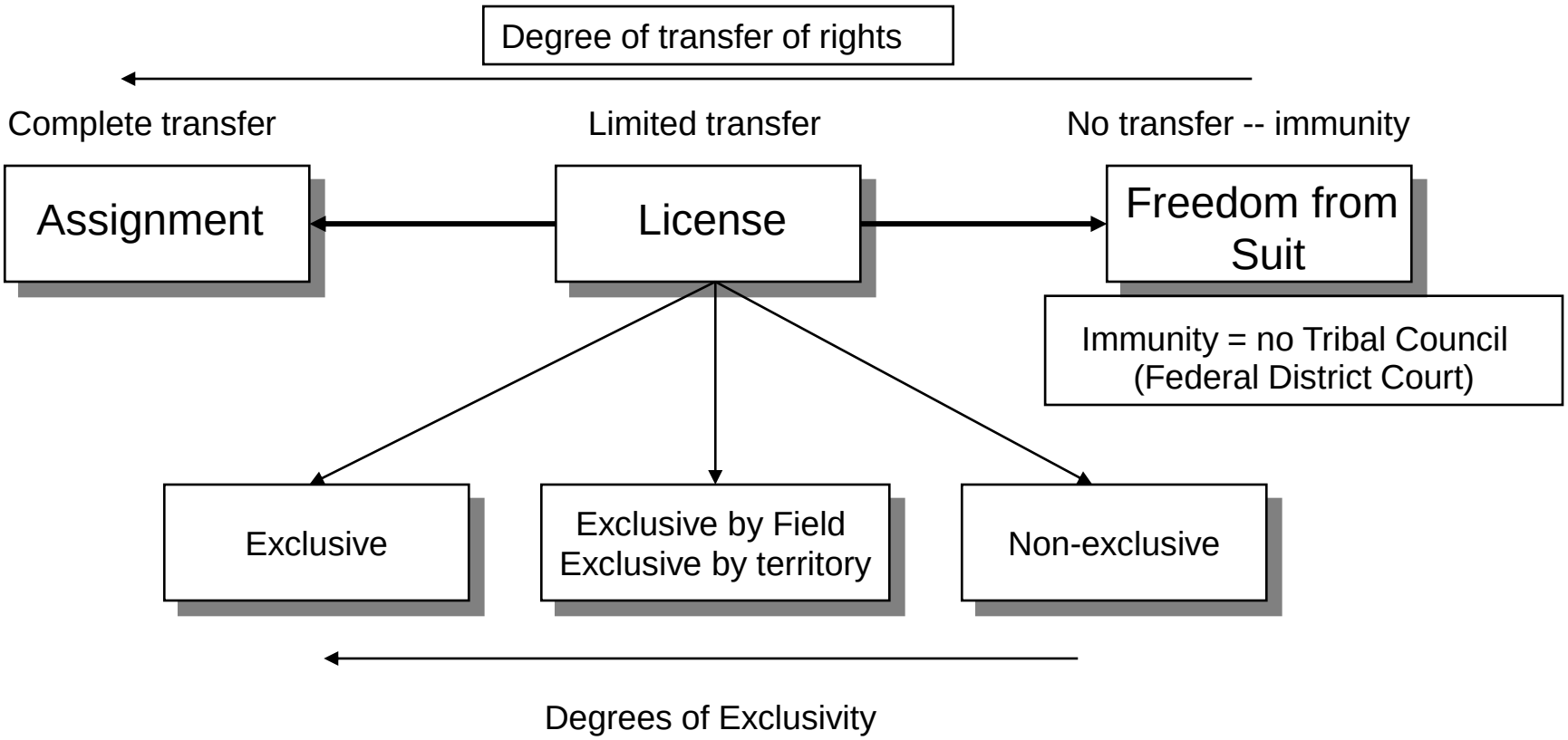
- Defined terms are either Capitalized or ALL CAPS
- A section of Definitions – either Article I or an Appendix

  Licensed **P**atents shall mean ……
- Some terms are defined in the text
  - In parentheses and quotation marks

    LICENSE AGREEMENT dated as of June 30, 2012 (the "Effective Date"), by and between Trustees of Boston University (the "University") and …..
- Complex agreements can have 200 Defined Terms

License Grant

Different Degrees of Rights Can be Granted



Licensing vs. Assigning

- In U.S., we don't assign
  - Bayh-Dole Act doesn't allow us to without permission of the Funding Agency
    - Won't give it
      - If Google can be founded based on an exclusive license from Stanford……..
- Other countries don't have this protection
  - Can come under pressure to assign
- Can write an assignment agreement with same payments as a license
- Difference is in the balance of power if things go wrong
  - Licensor can terminate unilaterally
    - Licensee may sue to prevent
  - An assignee has to agree to assign back

Licensing Strategy

Develop the Licensing Strategy

- The fundamental question:
  - Are we going to license this to an existing company?
  - Or a new company?
- Truly revolutionary inventions frequently need a new company
- Incremental inventions are licensed to existing companies

Licensing Strategy

- Are there multiple products that come from the technology?
  - If answer is “Yes”, which market is most attractive?
  - Do we need separate sets of patent claims to protect each market?
- Are the products used in the same industry?
  - If so, can the same company exploit them?
  - If answer to either is “No”, then we will need to license by field of use and find multiple licensees

Licensing Strategy

- Does the license(s) need to be exclusive?
  - Maximizes the incentive to the licensee
  - Maximizes the risk to the licensor
    - Maximizes the potential return to the licensor
      - Generally, exclusive licenses have higher royalty rates than non-exclusive
- Does the technology provide everything that's needed for a finished product?
  - If so, do we want to provide the maximum incentive for a licensee to invest in developing the technology?
    - Exclusivity provides that
- Is there a clear market leader?
  - They may be the most attractive / only viable licensee
- Is it a crowded market?
  - If so, #2 or #3 may be a more motivated licensee

We're only no.2

We try harder

Licenses Granted in US

- 20% start-up companies
- 50% small companies
- 30% large companies

- 33% exclusive
  - Start-Ups almost always need an exclusive license to all fields of use
- 67% non-exclusive

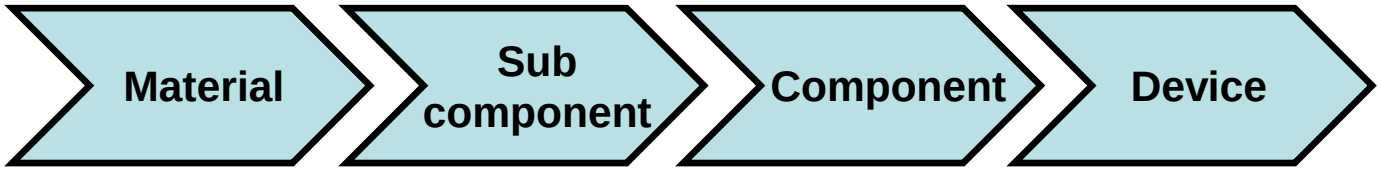
Source: AUTM Annual Licensing Activity Survey

Licensing Strategy

- What are the key steps the licensee needs to do to get a product into the market
  - These will become your due diligence mechanisms
  - Should have at least one milestone each year
    - Perhaps more in first year
    - Ensure that licensee is developing the technology
    - Terminate the license if not
  - If start-up, include corporate development milestones
    - Fund raising
    - Hiring of key individuals

Value Chain Analysis

- Where in the supply chain does your technology fit?
- How far forward in the supply chain does the technology's value add let you integrate?
  - The further forward you go, the more value you capture
  - e.g., a new material



- Most supply chains have been so disaggregated that you can usually find a contract manufacturer in any segment

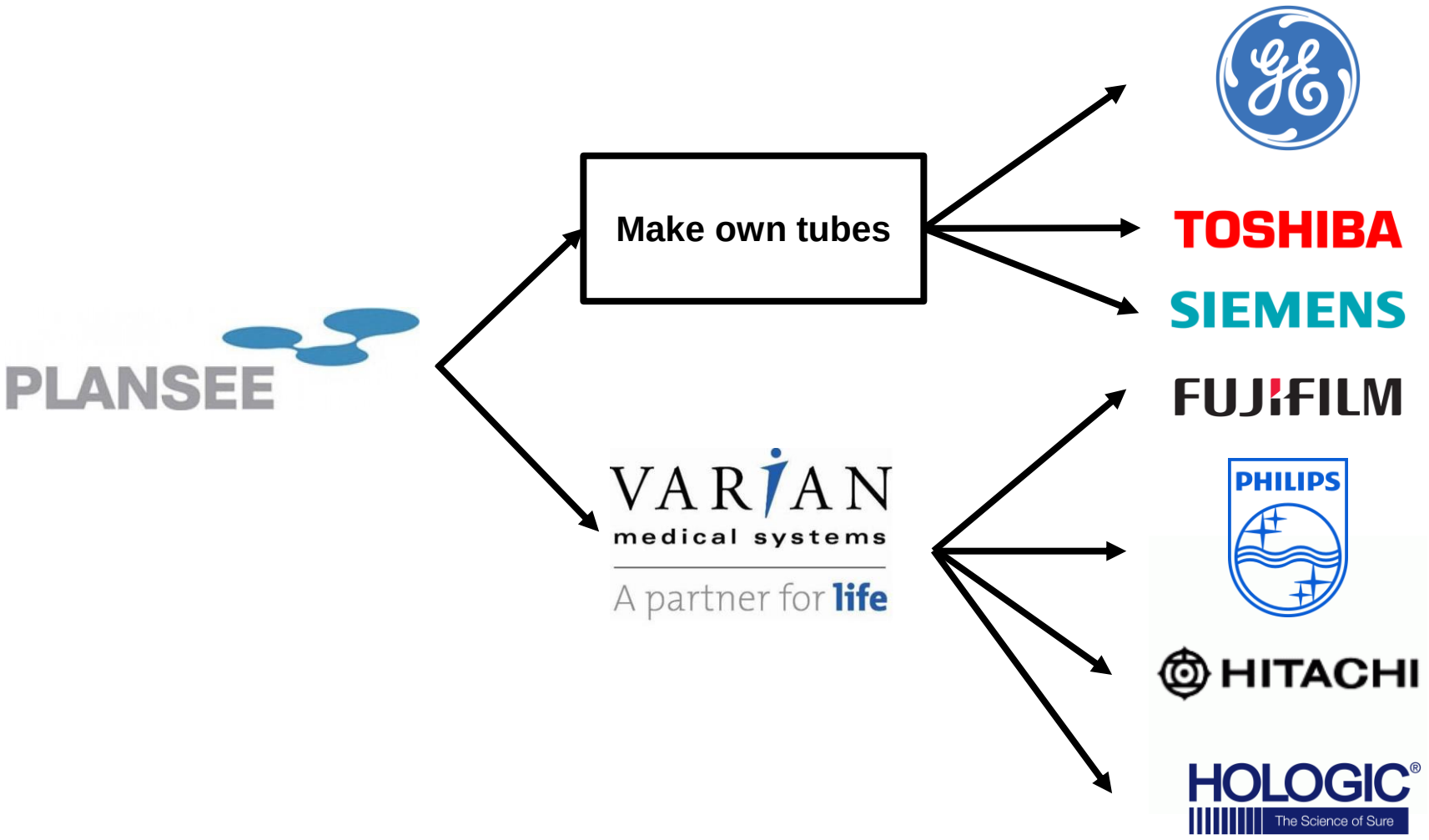
Example: A Material for an Improved X-Ray Anode

- The supply chain options:
  - Make the material and sell to anode manufacturers
  - Make anodes and sell to X-ray tube manufacturers
  - Make X-ray tubes and sell to X-ray system manufacturers
  - Make and sell X-ray systems to healthcare providers
- The supply chain realities:
  - Only a few manufacturers of X-ray systems
  - Only one manufacturer and seller of X-ray tubes
    - Some system manufacturers make their own X ray tubes
  - Only one manufacturer of anodes

X-Ray Anode Manufacturers

X-Ray Tube Manufacturers

X-Ray Machine Manufacturers



Example: A Material for an Improved X-Ray Anode

- The only strategic options:
  - Make anodes and sell to the four tube manufacturers; or
  - Make the material and sell to the one anode manufacturer
- Licensing strategy:
  - Determine whether the tube manufacturers are happy with Plansee
    - Monopolists can build up ill-will
  - If they are happy:
    - Only option is to sell to Plansee
  - If they're not happy:
    - **MAY** be an opportunity for a start-up anode manufacturer

License Grant

- University hereby grants an Exclusive License to make, have made, use, have used, sell, have sold and import Licensed Products under the Patent Rights within the Licensed Field
- Right to grant sublicenses
  - Don’t require prior approval of sublicensees
- No exclusivity for know-how (“technology”)
- Certainly no license to trade secrets
- May not include rights to improvements
  - Certainly time limited

Licensed Patents

- What the rights are being granted to
- Identified by number and title
- Mechanism to capture continuations, continuations-in-part and foreign counterparts

Licensed Field / Field of Use

- The subset of all the possible uses of the technology that the Licensee is getting rights to
  - State what is affirmatively included
  - State what is affirmatively excluded
    - e.g., any planned or previously granted fields of use
      - Reproduce the exact wording of the other affirmative grants

      Licensed Field shall include all products intended for human therapeutic and prophylactic use

Licensed Field/Field of Use

- The subset of all the possible uses of the technology that the Licensee is getting rights to
  - State what is affirmatively included
  - State what is affirmatively excluded
    - e.g., any planned or previously granted fields of use
      - Reproduce the exact wording of the other affirmative grants

        Licensed Field shall include all products intended for human therapeutic and prophylactic use, excluding any products in which a DNA construct is introduced into a human patient using a viral vector or by direct injection of a DNA construct ("Gene Therapy")

Licensed Field/Field of Use

- The subset of all the possible uses of the technology that the Licensee is getting rights to
  - State what is affirmatively included
  - State what is affirmatively excluded
    - e.g., any planned or previously granted fields of use
      - Reproduce the exact wording of the other affirmative grants

        Licensed Field shall include all products intended for human therapeutic and prophylactic use, excluding any products in which a DNA construct is introduced into a human patient using a viral vector or by direct injection of a DNA construct ("Gene Therapy") and furthermore shall exclude all products intended for non-human animal therapeutic and prophylactic use ("Veterinary Uses")

Territory

- Don’t include more than they can reasonably sell in
- Major territories:
  - US
  - Europe
  - Japan
  - China
  - India
- Make or sell?

Fees, Royalties and Payments

- Royalty base
  - Net Sales of Licensed Products
  - Kit deduction
    - Combination products
    - Apportion Net Sales in ratio of individual prices if sold separately
    - If not sold separately, very difficult
      - Apportion in ratio of fully burdened manufacturing cost
      - Apportion equally
      - May just need to specify “good faith”

Fees, Royalties and Payments

- Royalty payment = Royalty Base x (Royalty Rate – Offset/Stacking) – Deductions
  - Limit stacking and deductions
- Non-Exclusive Licensees may demand a “Most Favored Nations” Clause
  - Nobody gets a lower rate
  - If they do, everybody gets the lower rate

Licensed Products

- Either identified by name
  - If licensed at a late stage when products are known

  or
- Covered by a Valid Claim of a Licensed Patent

  or
- Any product which would, but for the license granted hereunder, infringe a Valid Claim of a Licensed Patent
  - Legally defined under the Patent Statutes (USC)

Patent Prosecution and Infringement

- University controls prosecution
- Reimbursement of patent expenses
  - Law firm bills university
  - University bills licensee
- Exclusive Licensee will want first right to sue for infringement
  - University must join the suit
    - We keep enough rights that exclusive licensee doesn't have standing to sue on their own
- Infringement costs paid by the company
  - Recovery distribution – (10% - 25% to University)
- University has second right to sue
  - Keeps all proceeds
- Non-Exclusive licensee has no right to sue

Obligations of the Parties

- Reports
  - Product Development
    - Due diligence
  - Product sales and Royalty payments
- Records for auditing
  - Right to audit
- Diligence
  - If you license exclusively, the licensee is your only hope for revenues
    - Best efforts to develop and commercialize Licensed Products
      - “Best efforts” is a legally defined term
    - Specific milestone events
      - Date
      - May have payments associated
- Manufacture substantially in the U.S. (for U.S. sales if excl. license)
  - Bayh-Dole requirement
- Patent/Copyright/Trademark notices

Representations and Warranties

- The guarantees
- Universities only represent that they have title to the Patent Rights
  - Not even complete title
    - May be additional inventors
- No other representations are made by the university, including:
  - Infringement of third party patents
  - Viability of technology
- Disclaimers of liability have to be in ALL CAPS and no smaller than 12 point
  - UCC requirement

Indemnification and Insurance

- Licensee accepts all liability for their use, and any sublicensee's use of Licensed Products
- Licensee must indemnify the University
- Product and other liability insurance is usually required
  - Large companies self-insure

Case Study:

- Memorial Sloan Kettering / Oclassen / Eli Lilly / Fialuridine / Hepatitis B

Confidentiality and Publication

- Reports, patent prosecution, & other information exchanged will be confidential
- University retains the right to publish its research related to the Patent Rights

Term and Termination

- Term of the License
  - Longer of:
    - Life of the last to expire patent included within Patent Rights
    - Expiration of any regulatory exclusivity (if healthcare)
    - 10 years from first commercial sale

    on a country by country basis
- Licensee is free to terminate the license at their option
  - Can't force them to continue to invest if they don't want to
- Termination fees might be required
  - Or return of the product including all the know-how they've created
    - Compensation for consumption of the patent life
- Termination by the University for breach and bankruptcy only
- Sublicenses in good standing continue, with Licensor replacing licensee
- Fully paid-up perpetual license after expiration of royalty term

Dispute Resolution

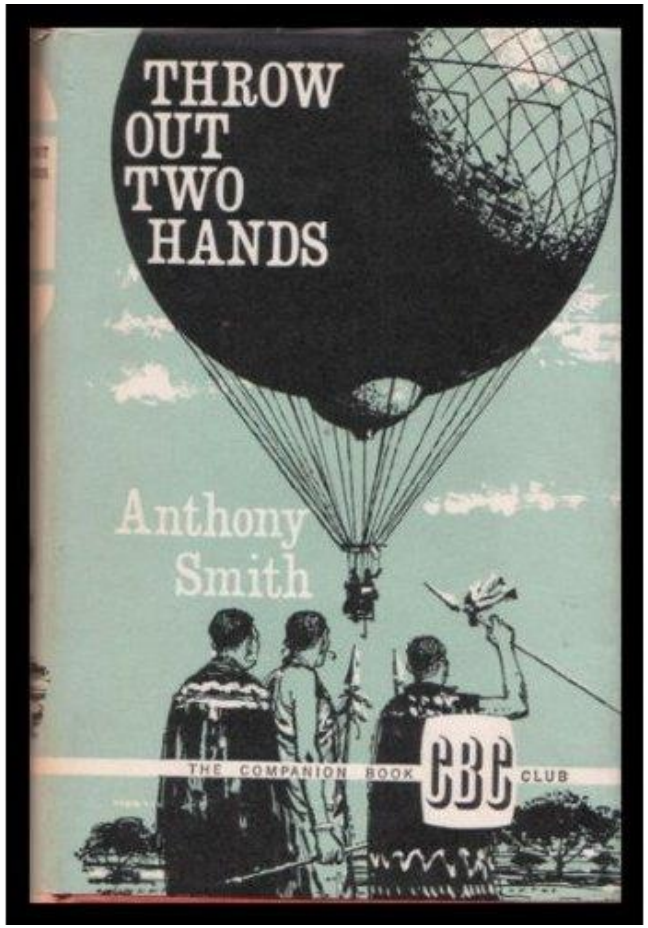
- "Summit Meeting"
- Mediation
- Arbitration
  - Binding or non-binding
- None – straight to Court
- International agreements usually specify arbitration
  - ICC Rules
  - WIPO Rules

Miscellaneous

- Notice
- Use of Name
- Governing Law
  - New York State a very popular choice for international agreements
- Assignment
  - With or without permission
  - Acquiror of the entire company
    - Of the entire business line

Best Practices / Lessons Learned

- Start with a good template
  - Everything is in there for a reason
- The licensor should do the first draft, starting from the template

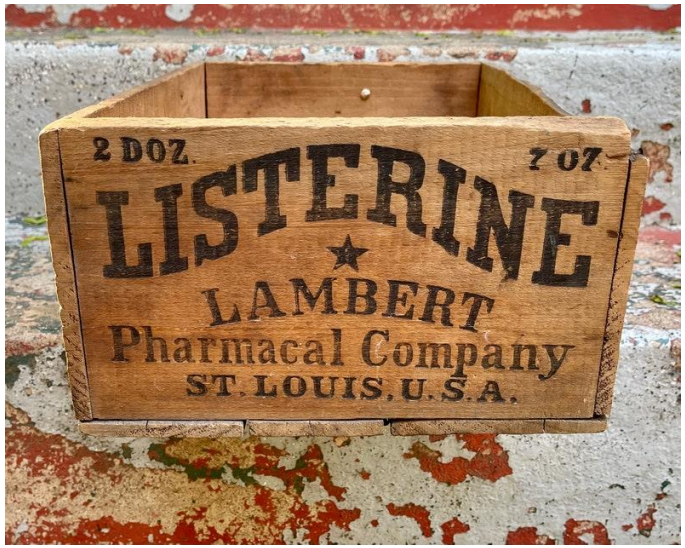


“The safety rules of ballooning are essentially a recapitulation of the accidents that have happened”

“The safety rules of licensing are essentially a recapitulation of the accidents that have happened”

Example: Listerine

- Invented in 1881
  - Dr. John Lawrence, St. Louis, MO
  - Licensed to pharmacist, Jordan Lambert
    - Trade secret formula
    - Founded Lambert Pharmacal Company



Entire Agreement

Know all men by these presents, that for and in consideration of the fact, that Dr. J. J. Lawrence of the city of St Louis Mo has furnished me with the formula of a medicine called Listerine to be manufactured by me, that I Jordan W Lambert, also of the city of St Louis Mo, hereby agree for myself, my heirs, executors and assigns to pay monthly to the said Dr. J. J. Lawrence his heirs, executors or assigns, the sum of twenty dollars for each and every gross of said Listerine hereafter sold by myself, my heirs, executors or assigns. In testimony whereof, I hereunto set my hand and seal,

Done at St Louis Mo. this the 20th day of April, 1881

Jordan W Lambert (Seal)

Example: Listerine

- Invented in 1881
  - Dr. John Lawrence, St. Louis, MO
  - Licensed to pharmacist, John Lambert
    - Trade secret formula
    - Founded Lambert Pharmacal Company
- Formula accidentally published prior to 1949
- Lambert merged with Warner-Hudnut in 1955 – Warner-Lambert
  - Stopped paying royalties
    - Trade secret they had bought was no longer a trade secret
  - Heirs sued
    - Judge agreed:
      - Agreement says: “As long as you sell, you pay”
        - Doesn’t say: “As long as it’s a trade secret you pay”
  - J&J still paying royalties
    - You can buy the rights to receive royalties on Listerine!

Questions?

Tea / Coffee

Session 4:
Socially Responsible Licensing

Agenda

- The importance of academic licensing policies
- The role of public sector in drug discovery
- The pharmaceutical industry from 35,000 feet
- Ways to encourage affordability
- The evolution of socially responsible licensing
- The Pandemic

The Zerit® / Yale Story

- AZT is a nucleoside analogue discovered as an anti-cancer drug at Michigan Cancer Center in 1964
  - Jerome Horowitz
  - Unpatented
- In 1985, Burroughs Wellcome conceived of the idea of using AZT to prevent HIV replication
  - Applied for method of treating patent
- Dr. Samuel Broder at NCI set up a screen to test for anti-retroviral activity
  - Demonstrated efficacy of AZT
- Subsequently showed several additional Horowitz compounds were effective
- Patented by NCI, licensed by NIST and successfully developed:
  - ddI (Videx, BMS)
  - ddC (HIVid, Roche)

The Zerit® / Yale Story

- Drs. Tai-Shun Lin and William Prusoff of Yale University discovered d4T's ability to treat HIV / AIDS
- Funding from NIH and BMS
  - Yale gave BMS an exclusive option to an exclusive license
- Yale filed for a method of treating patent
  - US patent 4,978,655 issued December 18, 1990
- Bristol-Myers Squibb exercised option
  - License signed on January 12, 1988
- License gave BMS right to determine where to file patents
  - BMS elected to file in Europe, Japan, Canada, etc.
    - Included S. Africa, Mexico, Egypt
- Received FDA approval June 1994

The Zerit® / Yale Story

- In 2000,Toby Kasper of *Médecins Sans Frontières* compiled a list of essential medicines that the world needed access to
  - Zerit® was on the list
- Started pushing for generic versions of anti-retrovirals in 2000
- CIPLA offered to supply d4T for 5 ¢/tablet
- 39 companies filed suit to prevent *MSF* buying generics
- MSF requested waiver of S. African patent
- Yale said they were powerless
  - BMS had an exclusive license

The Zerit® / Yale Story

- Enter Amy Kapczynski 

- First year Yale Law Student
- Had met Toby at an AIDS conference in Durban in July 2000
- Toby identified that Yale held the patent and contacted Amy
- Secured support of Prusoff and Michael Merson
  - Dean of Yale School of Public Health
    - Former head of WHO HIV / AIDS program

The Zerit® / Yale Story

- Got a story in the student newspaper March 2, 2001
- Organized a petition
  - Got 600 signatures
- *NYT* ran a story March 11, 2001 – front page Technology Section

Yale Pressed to Help Cut Drug Costs in Africa

By DONALD G. McNEIL Jr.
Published: March 12, 2001

PARIS, March 11— Trying a new tack to drive down the price of AIDS medicines, the medical charity Doctors Without Borders has asked Yale University to permit South Africa to import a generic version of a drug on which Yale holds the patent.

The university, citing a patent contract with Bristol-Myers Squibb, has refused. But the Yale press office released a brief statement on Friday saying Yale had removed all barriers to Bristol-Myers in making the drug readily available in South Africa and hoped it would do so.

A group of Yale law students, distressed that their university looks complicit in keeping the drug out of reach of thousands of dying South Africans while getting $40 million a year in license fees, have been planning to pressure Yale.

A Bristol-Myers spokesman said the company was planning action because of the Yale protest, but declined to describe it.

The drug in question is d4T, an antiretroviral drug also known as stavudine or by the brand name Zerit. It was one of the first components of the triple-therapy AIDS cocktail

The Yale Story

- Got a story in the student newspaper March 2, 2001
- Organized a petition
  - Got 600 signatures
- *NYT* ran a story March 11, 2001 – front page Technology Section
- On March 14, 2001 BMS announced it would not enforce the patent in S. Africa and offered to sell d4T for 7.5¢/tablet

Maker Yielding Patent in Africa For AIDS Drug

By MELODY PETERSEN and DONALD G. McNEIL Jr.
Published: March 15, 2001

Bristol-Myers Squibb said yesterday that it would no longer try to stop generic-drug makers from selling low-cost versions of one of its H.I.V. drugs in Africa, making it the second drug company in a week to greatly change its policies in the face of the AIDS epidemic.

It is extremely rare for a drug maker to yield its rights over a patent, which gives it a monopoly in selling a drug. But the AIDS crisis has subjected the industry to critiism that its prices are keeping millions of poor people in Africa from getting vital care.

Bristol-Myers holds the patent on a drug known as d4T or stavudine, which is sold under the brand name Zerit, and said it would not use its legal rights to keep lower-cost generic versions of this drug out of South Africa or any other African nation.

Yale University, which owns the rights to the Zerit patent with Bristol-Myers, said it would go along.

Bristol-Myers, based in Manhattan, also said it would sharply reduce the price of Zerit and another AIDS drug, ddI or didanosine, which is sold as Videx, in Africa, to a combined price of $1 a day. The company does not own the patent to Videx.

In the United States, by contrast, one day's dose of the two drugs costs $18, the company said.

Bristol-Myers's announcement goes beyond sharp price cuts taken last week by Merck &

The Zerit® / Yale Story

- Got a story in the student newspaper March 2, 2001
- Organized a petition
  - Got 600 signatures
- *NYT* ran a story March 11, 2001 – front page Technology Section
- On March 14, 2001 BMS announced it would not enforce the patent in S. Africa and offered to sell d4T for 7.5¢/tablet
- Eventually signed a non-suit with Aspen Pharmaceuticals
- Within a month, Bristol-Myers Squibb, GlaxoSmithKline, Pfizer, Abbott, Hoffman-La Roche, and Boehringer Ingelheim issued a statement promising to lower costs in developing nations
- Lawsuit dropped
- Amy's now on the faculty of UC Berkeley Law School

Lessons Learned

- Does this sound familiar?
- This could happen at any university **TODAY**
  - We routinely give an exclusive option to an exclusive license to industrial research sponsors
  - Our licenses always give the licensee the right to choose where to file patents overseas
    - Generally, universities won't even file foreign patents without a licensee to reimburse
- It's imperative that we include global health provisions in our licenses when licensing health care inventions with relevance to both the developing and the developed world
- Enormous good came from the Zerit® case
  - May not have felt good to Yale at the time
    - And in the continuing tellings of the tale!

Universities and Drug Discovery

SPECIAL ARTICLE

The Role of Public-Sector Research in the Discovery of Drugs and Vaccines

Ashley J. Stevens, D.Phil., Jonathan J. Jensen, M.B.A., Katrine Wyller, M.B.E., Sabarni Chatterjee, M.B.A., Ph.D., and Mark L. Rohrbaugh, Ph.D., J.D.

ABSTRACT

BACKGROUND

Historically, public-sector researchers have performed the upstream, basic research that elucidated the underlying mechanisms of disease and identified promising points of intervention, whereas corporate researchers have performed the downstream, applied research resulting in the discovery of drugs for the treatment of diseases and have carried out development activities to bring them to market. However, the boundaries between the roles of the public and private sectors have shifted substantially since the dawn of the biotechnology era, and the public sector now has a much more direct role in the applied-research phase of drug discovery.

METHODS

We identified new drugs and vaccines approved by the Food and Drug Administration (FDA) that were discovered by public-sector research institutions (PSRIs) and classified them according to their therapeutic category and potential therapeutic effect.

RESULTS

We found that during the past 30 years, 153 new FDA-approved drugs, vaccines, or new indications for existing drugs were discovered through research carried out in PSRIs. These drugs included 93 small-molecule drugs, 36 biologic agents, 15 vaccines, 8 in vivo diagnostic materials, and 1 over-the-counter drug. More than half of these drugs have been used in the treatment or prevention of cancer or infectious diseases. PSRI-discovered drugs are expected to have a disproportionately large therapeutic effect.

CONCLUSIONS

Public-sector research has had a more immediate effect on improving public health than was previously realized.

From the Institute for Technology Entrepreneurship and Commercialization (A.J.S.) and Office of Technology Development (A.J.S., J.J.J.), Boston University School of Management, Boston; the Norwegian Radium Hospital Research Foundation, Oslo (K.W.); and the Office of Technology Transfer, National Institutes of Health, Bethesda, MD (S.C., M.L.R.). Address reprint requests to Dr. Stevens at Boston University School of Management, 53 Bay State Rd., Boston, MA 02215, or at astevens@bu.edu.

N Engl J Med 2011;364:535-41.

Number of Products

Type of Product	Number
New Chemical Entity	93
Biologic	36
Vaccine	15
Over the counter	1
In-vivo diagnostic	8
Total	153

- Update investigates the contribution of public-sector research institutions (PSRIs) outside the US to pharmaceutical innovation.

Bringing the Study up to Date and Expanding it

- 357 FDA approved drugs, biologics, vaccines and *in vivo* diagnostics[1]

U.S.	242
Non-U.S.	72
Both	43
	357

[1] Unpublished data A.J. Stevens, D.E. Benson, S.E. Dodson, J.J. Jensen and M. Rohrbaugh

Number of Products

	Number
New Chemical Entity	231
Biologic	75
Vaccine	22
Over the counter	2
NCE / OTC	2
In-vivo diagnostic	25
Total	357

Therapeutic Categories

Therapeutic Area	Number	%
Oncology	85	23.8%
Infectious Disease	68	19.0%
Metabolic	48	13.4%
CNS	45	12.6%
Cardiology	22	6.2%
Renal	14	3.9%
Dermatology	14	3.9%
Gastroenterology	12	3.4%
Women's Health	11	3.1%
Ophthalmology	9	2.5%
Immunology	7	2.0%
Anaesthesiology	6	1.7%
Pulmonary	5	1.4%
Urology	4	1.1%
Allergy	2	0.6%
Dental	2	0.6%
Emergency Medicine	2	0.6%
Otolaryngology	1	0.3%
Total	357	

Discovering Institutions

Institution	Number
National Institutes of Health	27
U. of California	21
Emory University	19
KU Leuven	14
Czech Academy of Sciences	12
Hans-Knoell-Institute Jena	10
Tufts Medical Center	10
Tufts University	10
U. of Toronto	10
Columbia University	9
Memorial Sloan Kettering	9
U. of Texas	9
Individual	8
Massachusetts General Hospital	8
Weizmann Institute	8

Discovering Institutions

Institution	Number
National Institutes of Health	27
U. of California	21
Emory University	19
KU Leuven	**14**
Czech Academy of Sciences	**12**
Hans-Knoell-Institute Jena	**10**
Tufts Medical Center	**10**
Tufts University	**10**
U. of Toronto	**10**
Columbia University	9
Memorial Sloan Kettering	9
U. of Texas	9
Individual	8
Massachusetts General Hospital	8
Weizmann Institute	**8**

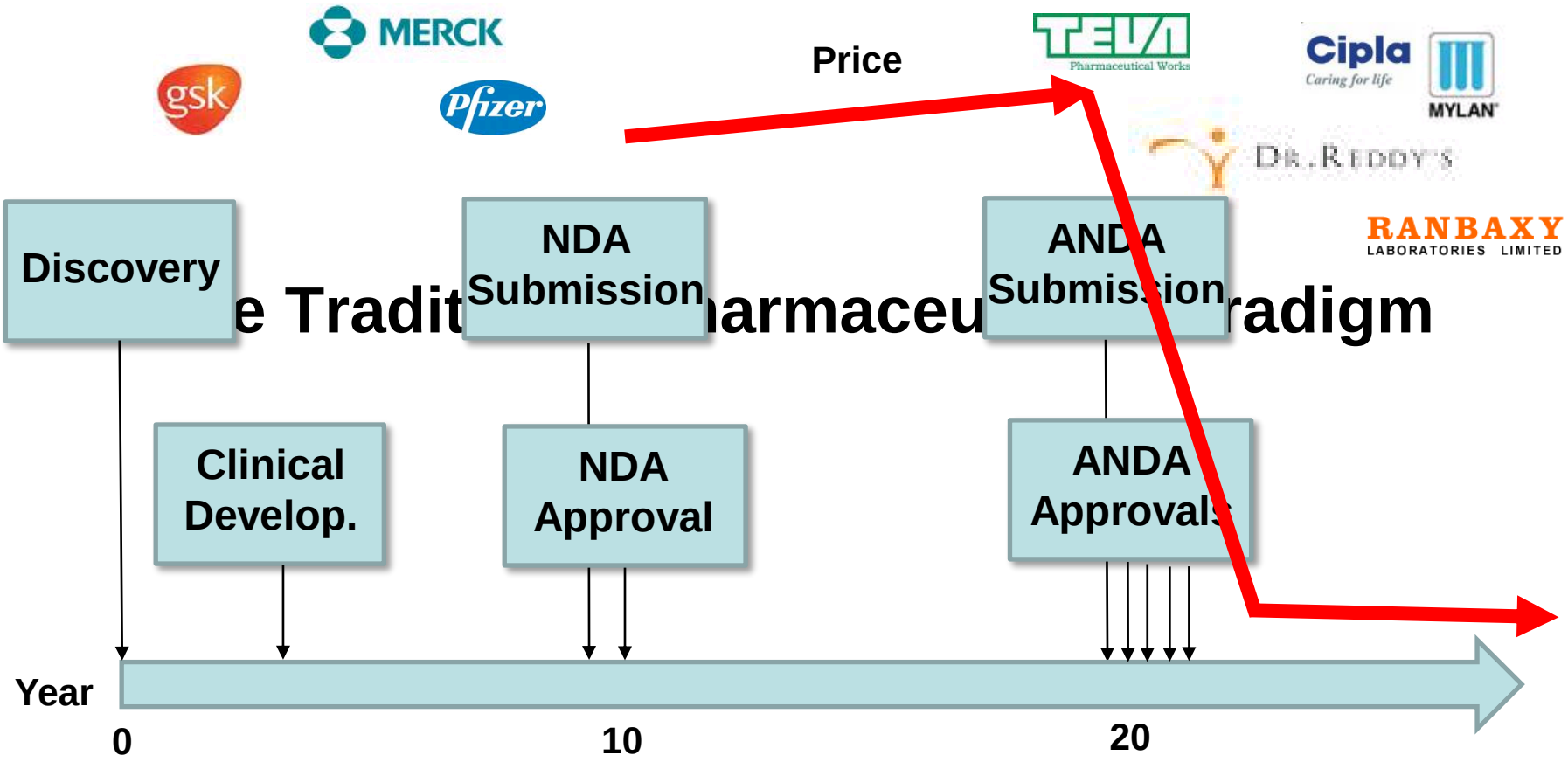
Discovering Countries

Country	No. of Drugs	%
US	285	66.6%
Canada	22	5.1%
UK	20	4.7%
Germany	18	4.2%
Belgium	15	3.5%
Japan	14	3.3%
Australia	13	3.0%
Czech Republic	12	2.8%
Israel	12	2.8%
France	8	1.9%
Sweden	4	0.9%
Switzerland	1	0.2%
China	2	0.5%
Holland	1	0.2%
Russia	1	0.2%
Total	428	

Emerging Economies

- Relatively unrepresented
  - Czech Republic a special circumstance
    - Highly productive collaboration with KU Leuven for anti-virals
  - China only 2
    - Both from military institutes
  - Russia only 1
    - Back in the USSR days
  - One case from an emerging economy
    - National Institute of Immunology, New Delhi
      - *Mycobacterium indicus pranii* (MIP)
        - Vaccine to prevent and treat leprosy
          - Adjunct to multi-drug regime
          - Only approved in India
          - Licensed to

The Pharmaceutical Industry



Global Health and Economics 101

Economics 101

- Monopolies result in high prices
- Competition results in low prices

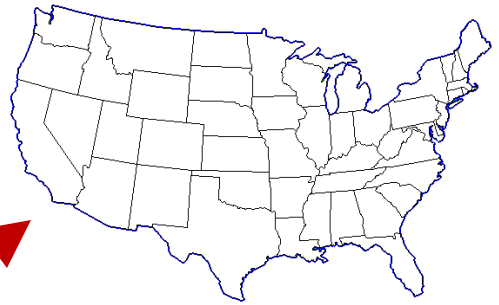
In Pharmaceuticals

- New, patent protected medicines are priced on a market value basis
- Older, patent-expired medicines are priced on a cost+ basis

The Global Health Challenges

- How do we make new, patent protected medicines available in developing countries at cost+ pricing?
- How do we develop treatments for diseases that aren't a problem in developed countries?

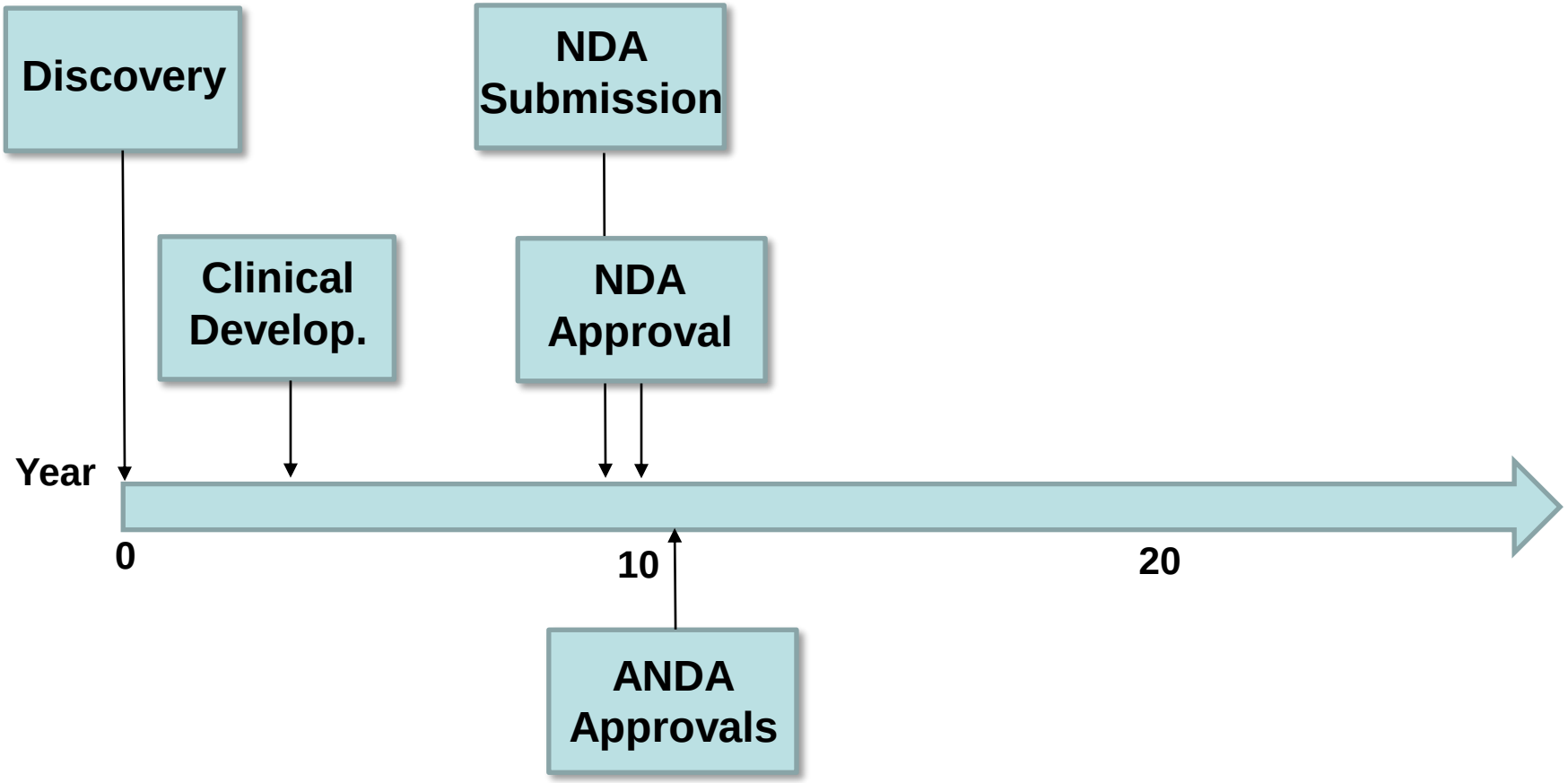
Let's Think About How a Public Sector Discovered Drug Gets to the Global Market



The Traditional Academic Development Model

How Do We Modify this Process to Achieve Affordability?

The New Pharmaceutical Paradigm



How Can We Achive This?

- We could try to change the patent system to achieve this
  - Or we could change the licensing system
- The problem isn't the patent system
  - Patents just give you control over what happens to your IP
  - An essential component of the innovation system
  - We should be very cautious about changing it
- It's much easier (and less risky!) to change licensing behavior
  - E.g. PCT Treaty signed 1970
  - Came into effect in 1978
- Bristol-Myers changed its policies in three days
- Are there licensing approaches we can develop?

Using Academic License Agreements To Promote Global Social Responsibility

By Ashley J. Stevens D.Phil (Oxon) and April E. Effort

I. Abstract

The impetus to use academic innovations to enhance peoples' lives in the developing world, which we term promoting Global Social Responsibility or "GSR," got its start with healthcare and the need to ensure affordable access to life saving medicines even during their period of patent protection in the developed world. However, academic innovation has the potential to advance living standards in the developing world in other ways in addition to healthcare, and it is equally important that academic institutions commit themselves to realizing this broader potential and adopt licensing approaches that anticipate these broader considerations.

The purpose of this article is to present (a) a business and licensing paradigm; and (b) a number of sets of simple, readily implementable language that academic institutions can choose from if they wish to ensure that inventions emanating from their research programs are used to improve the human condition in developing countries.

We show how current academic licensing best practices leave academic institutions vulnerable to a repetition of the Zerit® story that attracted such negative publicity for Yale and Bristol-Myers Squibb in 2001.

We show that it is possible to achieve socially positive licensing outcomes without detracting from academic institutions' ability to license their innovations and get them developed. Our research has shown that the academic community is at the very earliest stages of including social responsibility in its licensing practices, and we identify the leading institutions and the approaches they are following to achieve these ends. We also show that the pharmaceutical industry is starting to move in the direction we advocate of its own volition.

Finally, we identify the risks from inaction—the potential for congressionally mandated amendments to the Bayh-Dole Act that we believe will make it significantly harder to license academic inventions in the first place.

II. Acknowledgements

We wish to thank the following for helpful discussions and contributing license language: Mark Anderson, Anderson and Company; Alan Bennett, University of California Davis; Ian Bell and Angus Livingstone, University of British Columbia; Seema Shah Basu and Frances Toneguzzo, Massachusetts General Hospital; Steve Ferguson and Mark Rohrbaugh, National Institutes of Health; Lauren Foster and Lita Nelsen, Massachusetts Institute of Technology; Tony Hickson, Imperial Innovations Group plc; Sarah Sorscher and Michael Steffen, Universities Allied for Essential Medicines and, respectively Harvard and Yale Law Schools; Todd Keiller, University of Vermont; Warren Kaplan, Gerry Keusch, Kevin Outterson and Christy Talley, Boston University; and Carol Mimura, University of California, Berkeley;. Finally we thank our colleague Janine Anderson, without whose meticulous proofreading no important document leaves our office.

■ Ashley J. Stevens, Technology Transfer, Office of Technology Development of Boston University, Executive Director, Boston, MA, USA
E-mail: astevens@bu.edu
■ April E. Effort, Technology Transfer Office of Technology Development of Boston University, Licensing Associate, Boston, MA, USA
E-mail: aeffort@bu.edu

III. Introduction

Starting in 2001 and driven by the controversy (discussed in detail below) surrounding the licensing by Yale to Bristol-Myers Squibb of what became the very important antiretroviral drug Zerit®, academic institutions identified the need to address the issue of affordable access to their innovations in developing countries in their licensing agreements.

The issue received new impetus in 2003 when the Bill and Melinda Gates Foundation launched its Grand Challenges in Global Health, and included a requirement for a Fair Access Policy as part of the proposal, to ensure that the resultant products would indeed benefit the world's poor.

More recently, this principle was enunciated as Point 9 in the Stanford University "Nine Points to Consider" document;[1] the document included model

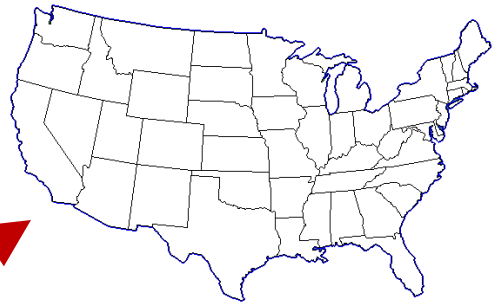
1. *http://otl.stanford.edu/tndustry/resources/whitepaper-10.pdf.*

Include Developing Country Milestone and Pricing

Licensee shall seek registration in a developing country by…….

Licensee shall make available in developing countries at prices no more than 50% more than fully burdened manufacturing cost

Don't Allow Patenting in Developing Countries



Cipla
Caring for life

RANBAXY
LABORATORIES LIMITED

VENTURE CENTER

FOCUS IP GROUP, LLC

Separate Licensees

MERCK

Cipla
Caring for life

RANBAXY
LABORATORIES LIMITED

FOCUS IP GROUP, LLC

VENTURE CENTER

Mandatory Sublicensing

MERCK

Cipla
Caring for life

RANBAXY
LABORATORIES LIMITED

FOCUS IP GROUP, LLC

VENTURE CENTER

Non-Assert

MERCK

Cipla
Caring for life

RANBAXY
LABORATORIES LIMITED

FOCUS IP GROUP, LLC

VENTURE CENTER

Issues

- Various definitions of “Developing Country”
  - Limit to public sector purchases
  - “Public sector” broadly defined:
    - Sovereign government
    - UN, WHO, World Bank agencies
    - Red Cross and Red Crescent
    - PPP’s
- Parallel imports
  - Require separate trade dress

AUTM

The Association of University Technology Managers

Advancing Discoveries for a Better World

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Must-read Article for AUTM Members
Be sure to read:
"Universities, Inventors, and the Bayh-Dole Act," by Sen. Birch Bayh, Joseph P. Allen and Howard W. Bremer Reproduced with permission from Life Sciences Law & Industry Report, 3 LSLR 1266 (Dec. 18, 2009). Copyright 2009 by The Bureau of National Affairs, Inc. (800-372-1033) http://www.bna.com

The Kauffman Foundation "Solution"
The *Harvard Business Review* has published its list of "Ten Breakthrough Ideas

What's Going On...

AUTM Licensing Activity Survey Summaries Now Available
Purchase the *AUTM U.S. Licensing Activity Survey: FY2008*
Purchase the *AUTM Canadian Licensing Activity Survey: FY2008*
Read more about the surveys

Register for the AUTM 2010 Annual Meeting
The AUTM 2010 Annual Meeting, Building a Stronger Community, will take place March 18 – 20, 2010 at the Hilton New Orleans Riverside, New Orleans, LA USA

Technology Transfer News

Read the Latest Technology Transfer Articles

University Inventions Sparked Record Number of Companies in 2008
Published in *The Chronicle of Higher Education* 2/15/10

UC Davis aims to turn more of its tech into business
Published in *University Business* 2/8/10

U-South Dakota researcher's germ-killing socks go into production
Published in *Serkadis* 2/3/10

Gecko's lessons transfer

AUTM Announces Global Health Initiative
AUTM announced the launch of a new Global Health Initiative that promotes licensing practices that support access to essential medicines by developing countries. The initiative includes a Global Health Toolkit created by AUTM members.
In keeping with this initiative, AUTM endorsed the *University Principles on Global Access to Medicines.* These principles were developed by a team that included AUTM leadership. Read the press release about the AUTM Global Health Initiative and AUTM's endorsement of the Principles.

Your institution can endorse the Principles here.

Read the Nine Points to Consider in Licensing University Technology

Endorse the Nine Points to Consider

Patent Reform
Patent Reform has been introduced into the 111th Congress AUTM has joined the Association of American Universities, the American

Read the latest blog from Alan Bentley about the hot debate topics at the 2010 Annual Meeting.

AUTM announces plenary speakers for 2010 Annual Meeting. Read the blog for details.

Will This Be Your First Annual Meeting?
Get the most out of your first meeting by learning from other members. Check out the blog posted by Vinay Tannan, Ph.D., Licensing Associate, UVA Patent Foundation. Vinay recalls his experience as a first time attendee at the 2009 Annual Meeting. Hassan Nagvi also shares his experiences as a first-time attendee.

Not Receiving AUTM E-mails?
Be sure to "white list" AUTM. For details, click here.

1/14/10

New License Agreement with University of Colorado Gives Viral Genetics, Inc., Right to Develop Cancer Therapies
Published on *PRNewswire* 12/8/09

Sathguru Signs MoU with University of Florida to Facilitate Technology Commercialization in Asia
Published on *BusinessWire India* 12/4/2009

Nikon Corporation Acquires License From Harvard University For 'STORM' Super Resolution Microscopy
Published on *PRNewswire,* 12/3/2009

Champions Biotechnology Enters into Licensing Agreement with Yale University and Southern Research Institute for the Repurposing of Bithionol for Oncology
Published on *PRNewswire*

Duke University and Jubilant Organosys Announce Intent to Enter Global Research and Drug Development Partnership
Published on *BusinessWireIndia.com* 11/11/09

Universities Endorse Global Access Principles
Published on *Bloomberg.com*

Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies

Background

Universities have a fundamental role in fostering public health. Their greatest contributions may occur through discovery of new knowledge, education of students, and dissemination of knowledge for others to build upon through publications, library collections, and most recently, open courseware.

In addition, universities in the developed world work to facilitate the commercialization of the health-related inventions of academic researchers by developing and disseminating these technologies for the public good. We have created new methods to deploy cutting-edge knowledge toward potential public benefit by enticing risk takers to invest in our early stage technology in the hope of possible downstream commercial applications. In recent years, the licensing practices involved in such commercialization have expanded to promote explicitly global access to university-developed technologies, ensuring that advances in health reach those who need them most.

This sensitivity to global health was reflected in *Nine Points to Consider in Licensing University Technology,* a statement endorsed by nearly seventy universities and other organizations since the spring of 2007. In acknowledgement that conventions in this field are ever evolving, and building on recent experience, the institutions named below believe a more concrete statement of goals as well as licensing practices would help to promote further progress in advancing health in developing countries. The principles

the Equitable Dissemination of Medical Technologies and invites your institution to do the same. These principles were developed by a team comprised of AUTM leaders, including Jon Soderstrom, AUTM immediate past president, of Yale University; and Ashley J. Stevens, AUTM president-elect, of Boston University. These guidelines discuss best practices for universities when considering the equitable dissemination of medical technologies.

Your institution can support these Principles by becoming a signatory to the document. Please ensure you have the necessary authority from your institution prior to signing.

Click here to download the Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies (PDF file)

Click here to endorse the Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies on behalf of your institution.

The AUTM Global Health Toolkit includes AUTM position documents, relevant papers and articles on global health issues and sample licensing clauses.

Current Signatories:

Institution	Signing Date
Association of University Technology Managers	11/09/2009
Boston Univ	11/09/2009
Brown Univ	11/09/2009
Harvard Univ	11/09/2009
Univ of Pennsylvania	11/09/2009
Yale Univ	11/09/2009
Oregon Health & Science University	11/09/2009
National Institutes of Health	11/10/2009
University of Illinois Chicago	11/10/2009
University of Illinois Urbana-Champaign	11/11/2009
Centers for Disease Control and Prevention	11/12/2009
University of Vermont and State Agricultural College	11/19/2009
Duke University and Duke Medicine	12/01/2009
University of British Columbia	01/10/2010
Bilkent University	01/27/2010
El Colegio de México	01/27/2010
New York University	02/04/2010
Tecnologico de Monterrey	02/13/2010

Boston University

- Adopted global health licensing principles in October 2007
- Non-assert approach
  - Limited to public sector programs
  - Trade dress protection

- 2.07 [If for a healthcare technology] Non-suit. University and Licensee on behalf of themselves and any successors-in-interest to the Licensed Products and Licensed Processes covenant that they will not, before or after the Effective Date of this Agreement, assert any claim of patent infringement (including direct infringement, contributory infringement, and induced infringement) under any of the patents in the Patent List, any Licensed Processes or any Orange Book Patent Right for manufacture, use, sale, offer for sale or importation of Licensed Products against any third party engaged in the manufacture, use, sale offer for sale, or importation of Licensed Products in or for Non-Suit Countries for sale to Public Sector entities. The above notwithstanding, this non-suit provision will only apply to products which when offered for sale to End Users are in a Trade Dress that is different from Licensee's Trade Dress in every respect.

Boston University

- Adopted global health licensing principles in October 2007
- Non-assert approach
  - Limited to public sector programs
  - Trade dress protection
- We included global health protections in:
  - Therapeutics and prophylactics
  - Diagnostics
- Not included in:
  - Tools
  - Devices
- Still going strong 14 years later
  - http://www.bu.edu/otd/files/2013/10/StartUp_ExclusiveLicense_12-10-12_Clean_ForDistribution.pdf

Key Learnings

- Global health protections can be included in standard forms of licensing agreement relatively simply
- Then it just becomes another business negotiation item
  - But a tough one!
- Must include in negotiations from day 1 in the term sheet

Where Does Industry Stand?

- Pharma's have accepted that they must also help develop drugs for LMIC's
  - Has emerged since 1999
    - E.g., Novartis Institute for Tropical Diseases in Singapore
      - Not-for-profit
      - ~200 employees
    - Novartis Institute for Vaccine Research in Sienna
- "No-profit No-loss" model
- Frequently hand over development to PPP's
  - Involve local companies, doctors, clinics
  - Supply the bulk of the clinical development funding

Gilead – HIV

- Founded 1986
- Multiple AIDS drugs on market
  - Viread® – NtTRI
  - Emtriva® – NRTI
  - FDC's
    - Truveda® – Viread® + Emtriva®
    - Atripla® – Truveda® + Sustiva® (BMS)
    - Etc.
- Pioneered "No Profit Pricing" in LMIC's by Big Pharma
- Licensed Indian generic manufacturers
  - Royalty bearing

Glaxo – HIV

- HIV drugs
- “Cost of Production + Distribution” Pricing in developing countries
- Voluntary licensing program to 9 generic producers
- Distinctive trade dress
  - Red
  - Trilingual packaging

Lilly – MDR-TB

- Two MDR-TB antibiotics
  - Capreomycin®
  - Cycloserine®
- Transferring manufacturing expertise to pharma's in highly impacted countries
  - Aspen Pharmacare –South Africa,
  - Hisun Pharmaceutical – China
  - Shasun Chemicals and Drugs –India
  - SIA International – Russia
- Manufacturing training at Purdue
- Supporting MDR-TB training and awareness programs

Tiered Pricing

- Pharmaceutical companies have adopted tiered pricing
  - Prices differ depending on economic development of a country
    - US highest
    - EU, Japan, Australia, Canada next
    - Middle economies
    - Lowest in under developed countries
- Devices also
  - Medtronic Healthy Heart For All initiative
    - Stents
    - Pacemakers

Patent Pools

Patent Pools

- Patent pools are formed to facilitate access to multiple patents
- First one was the Sewing Machine Patent Pool – 1856
  - Aircraft patent pool established in 1914
    - Deadlock between Wright Brothers and Curtis Aircraft Company
      - Aircraft desperately needed for WW1
- More recently associated with electronics standards – e.g., MPEG 2
- Proposals started to be made to form patent pools as a repository for global health rights.
  - UNITAID TOGETHER TO HEAL
  - emila The Essential Medical Inventions Licensing Agency

- International organization founded and funded by UNITAID
  - $4 million
    - 2010
- Initial focus HIV
  - TB, malaria and Hepatitis C added
    - 2015
  - Now working on mRNA
- Drug producers license to MPP
  - In defined LMIC territories
    - Currently 22 licensors
  - Agreement includes non-negotiable sublicensing terms
  - MPP finds sublicensees
  - More under COVID

- Impact:
  - Currently 57 generic producers and product developers
    - 14 countries
  - 148 countries have benefitted
  - 35 billion doses of drugs administered (2010-2022)
  - $1.5 billion projected savings (through 2022)
    - By the poorest people and countries of the poor
    - $3.5 billion savings projected through 2030
  - 170,000 lives saved

And then the Pandemic Hit

- On April 7, 2020, Harvard University, Massachusetts Institute of Technology, Stanford University issued a COVID-19 Technology Access Framework:
  - Pledged to license any COVID-19 related technologies "quickly, non-exclusively and royalty-free for the duration of the pandemic and for a short period thereafter"
  - 20 additional institutions have signed on
- On April 17, 2020, autm published its "COVID-19 Licensing Guidelines"
  - Essentially identical to Harvard/MIT/Stanford
    - 95 institutions have signed on
    - Some outside U.S.

Some of Academia's Contributions to the Pandemic

- UNIVERSITY OF OXFORD
  - Created adenovirus-based vaccine (Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant]))
    - Based on work targeting SARS, MERS, Zika, Ebola, etc.
  - Partnered with AstraZeneca
    - Co-developed
    - $10 million upfront, $60 million in milestones
    - 6% royalty
      - Royalty-free for duration of the pandemic
      - AZ will sell at zero profit in LMIC's **IN PERPETUITY**

Some of Academia's Contributions to the Pandemic

UNIVERSITY OF OXFORD

- Most important vaccine in developing world
  - Can be stored in a refrigerator
  - Manufactured by SERUM INSTITUTE OF INDIA Cyrus Poonawalla Group
  - Also licensed to:
  - mAbxience From lab to life
    - Argentina
    - API
  - LIOMONT
    - Mexico
    - Formulation, F&F
      - EUA from WHO

Baylor College of Medicine / Texas Children's

- CORBEVAX
  - Subunit vaccine
    - Unpatented
  - Licensed to:
    - Biological E. Limited
      Celebrating Life Every Day
      - India
    - bioFarma
      - Indonesia
    - Incepta
      - Bangladesh
    - ImmunityBio
      - Africa

Other Vaccines

- Beth-Israel Deaconess Medical Center, Boston
  - Adenovirus
  - Licensed to J&J
- mRNA Vaccines
  - Moderna
    - Designed jointly with NIAID
  - Both Moderna and Pfizer/BioNTech
    - LNP delivery
      - Originated at U. British Columbia
    - RNA pseudouridine substitution technology
      - Weissman / Karikó – U. of Pennsylvania
- BioNTech just announced mobile manufacturing units
  - No profit manufacturing
    - Rwanda, Senegal, Ghana

Drugs

- Lagevrio®
  - Molnupiravir
    - Discovered at Emory
      - Anti-viral drug discovery powerhouse
    - Licensed to DRIVE LLC
      - Wholly-owned drug development LLC
        - Phase 1
      - Licensed to Ridgeback Therapuetics
        - Phase 2
      - Partnered with Merck
        - Approval
      - Licensed to Medicines Patent Pool for LMIC's
        - Royalty-free for the duration of the pandemic
        - 35 sublicensees already

Diagnostics

- UC Berkley
  - Pioneer in socially responsible licensing policies
  - Co-discovered CRISPR
    - Set up CRISPR
      - Cas9
  - Discovered Cas12
    - Licensed to Mammoth Bio
      - Global health protections
    - Developed rapid diagnostic DETECTR BOOST®
      - Competitive with PCR
      - Partnered
        - Agilent to improve speed
        - GSK for OTC

Diagnostics

- Yale / National Basketball Association
  - SalivaDirect® COVID test
    - Dozens of labs authorized
- McGill
  - All Canadian PCR tests were imported
    - Created Canadian PCR test
      - Equivalent to imports
        - EUA

Entering the Supply Chain

- Dalhousie, Nova Scotia
  - Testing PPE imports into Canada
- Columbia
  - Designed face masks for 3D printing
    - Own machines originally
    - Added contract manufacturers
      - Millions manufactured
- U. of Calgary
  - Manufactured ventilators

Further Reading

- *"Intellectual Property Management in Health and Agricultural Innovation"*

  (aka the MIHR Handbook)

  ed. Anatole Kratinger *et al.*

- *http://www.iphan*

Day 2

Session 5
Over view and Introduction to Valuation Methodologies

The Basic Ways to Approach Valuation -- Economist's Perspective

- Cost
- Income
- Market

The Basic Ways to Approach Valuation -- the Licensing Guy's Perspective

- Cost
- Rules of Thumb
- Industry Standards – Comparables
- Ranking/Rating
- Discounted Cash Flow / NPV Split
- Monte Carlo
- Auction
- Common sense
- Equity

Today

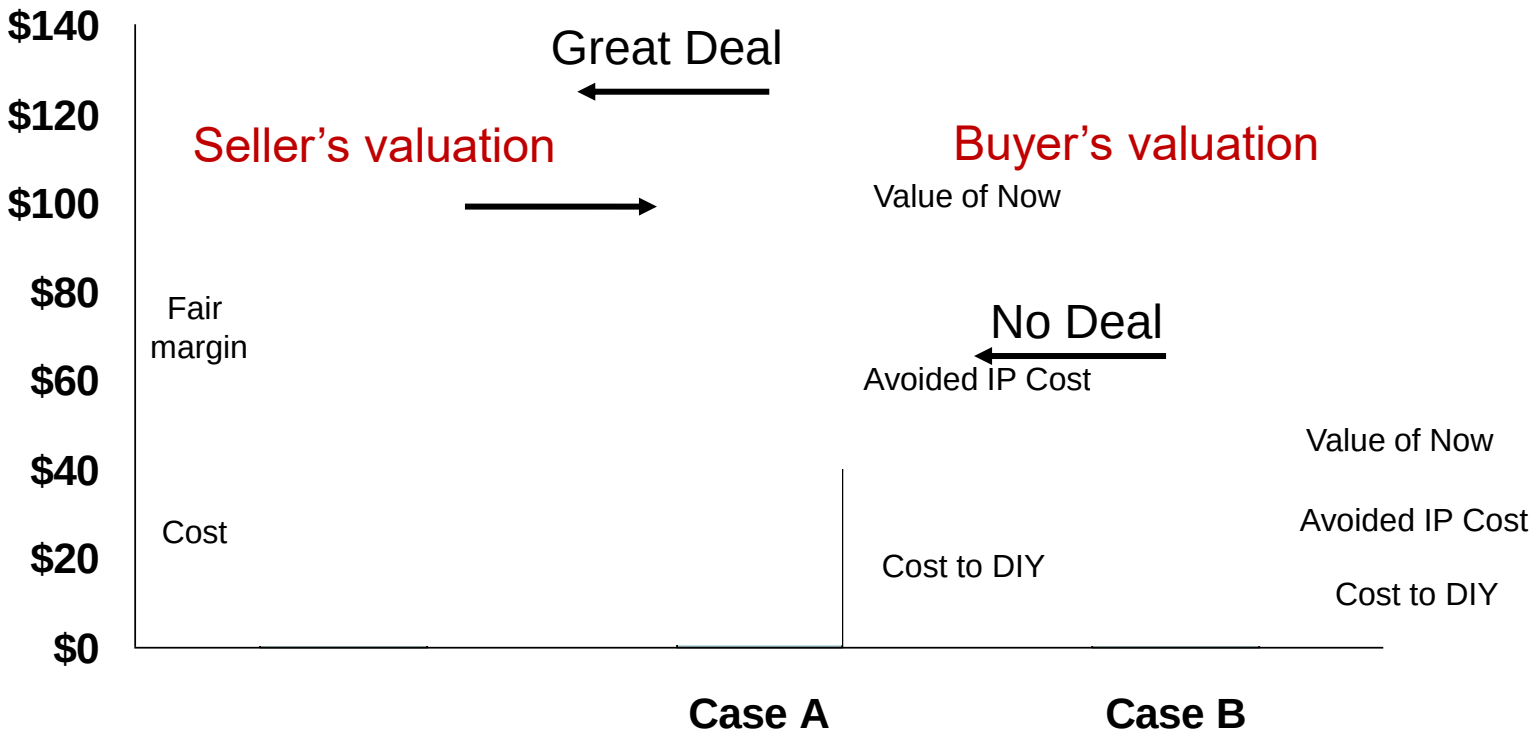
- Cost
- Rules of Thumb
- Industry Standards – Comparables
- Discounted Cash Flow / NPV Split

Look Back -- Cost

Look Back -- Cost

- Cost to develop plus a return
- Is cost to develop relevant?
  - Would you want to or be able to sell a used lottery ticket for what you paid for it?
  - Wasn't the technology developed with a GRANT?
- Two areas where cost enters in academic license negotiations:
  - Sunk patent costs
  - Relative ownership in a collaboration

Cost Driven Negotiation



Examples of Cost-Based Valuations

- U. of Minnesota and Penn State sponsored research models
  - Sponsor can get a fully paid up license for an extra 10% of the research costs
    - 10% of the **fully loaded** costs, including IDC
- Disease foundation funding model
  - Demand royalties in return for their funding
    - Royalties typically capped at 2-3x amount invested

Look to your Hand – Rules of Thumb

-- the 25% Rule

A Fundamental Principle of Technology Valuation

The Goldscheider Principle

(aka the 25% Rule)

"The Licensor should receive 25% and the Licensee should receive 75% of the pre-tax profits from a licensed product"

The 25% Rule

- Based on empirical observations
  - 18 worldwide licenses by Swiss subsidiary of US TV company PhilCo starting in 1959
  - Complete IP portfolio - patents, ongoing know-how, trademarks, copyrighted product materials
  - Licensees made ~20% pre-tax profit, paid 5% royalty; were either #1 or #2 in their market despite strong competition
    - 3 year term, so readily renegotiable if terms inappropriate
    - Happily renewed the licenses
  - Concluded that the licenses resulted in successful, long term win-win relationships
- Applicable to fully enabling technology
  - Need to prorate if other IP also needed
- Applied to fully-loaded pre-tax profits, not gross margin

Application

- Expressed as a % of net sales in license

  Royalty rate = 25% x expected pre-tax profit margin

- Example for a patent that fully enables the product:

  $200 sale price

  $100 Cost of Goods Sold (COGS)

  $50 SR&A

  = $50 Pre-tax Profit

  Patent owner share: 0.25 x $50 = $12.5

  Royalty = $12.5 / $200 = 6.25%

  Patent 75% enables product: Royalty = 4.69%

  Patent 50% enables product: Royalty = 3.13%

  Patent 10% enables product: Royalty = 0.63%

Application

- Good starting point for negotiation
  - But almost never the final rate agreed to
- Adjusted according to “enabling value” (%)
  - Typically after analysis of:
    - Manufacturing cost,
    - Market pricing dynamics
    - Value-add by licensee….
- Round off the numbers

  4.5% not 4.69%

  3.0% not 3.13%

  0.5% not 0.63%
- Limited value in academic licensing negotiations because of early stage
  - Incomplete cost data available
  - Very helpful when you’re licensing to a new industry

The 25% Rule and the Supreme Court

- In 2011 *Uniloc vs Microsoft* decision, Supreme Court determined that the 25% Rule was too imprecise an instrument to compute damages in infringement cases;
  - Goldscheider wrote a passionate defense in *les Nouvelles*
    - To no avail
    - Died July 2012
- Still a valid and important methodology in licensing

Other Examples of Risk Transfer Revenue Sharing

- The 25 Percent Rule type of split shows up in different sectors
  - Seems to be frequently perceived as “fair” when the future risk is transferred from one party to another
  - Our own royalty sharing policies
    - The inventor has largely completed their part
    - The Institution is taking on the financial risk of patenting and marketing
    - Common income sharing arrangements:
      - 1/3rd / 1/3rd / 1/3rd
      - 25% / 25% / 25% /25%

Other Examples of Risk Transfer Revenue Sharing

- Sublicense Income Sharing
  - Licensor's investment is complete
  - Licensee is taking the technology forward
    - 25% is a good starting point for negotiating sublicense income sharing

Other Examples of Risk Transfer Revenue Sharing

- Oil and gas royalties
  - The landowner has made its investment in buying the land
    - Will make no contribution to extracting the resources
    - Oil / gas company takes on the financial risk of drilling
  - Royalty rates:[1]
    - Federal land 12.5%
      - First Biden auction 18.75%
    - Federal waters 12.5-18.75%
    - State land 16.67-20%
    - Private land 12.5-25%

[1] https://www.doi.gov/sites/doi.gov/files/report-on-the-federal-oil-and-gas-leasing-program-doi-eo-14008.pdf

Other Examples of Risk Transfer Revenue Sharing

Table 1: Technology Fee for Biotech Planting Seed in Argentina

Year	Price of Biotech Seed US$/Ha		
	Bollgard	Roundup Ready	Bollgard + Roundup Ready
1998/99	76.0	Not approved	-
1999/00	70.0	Approved	-
2000/01	60.0		-
2001/02	60.0	30.0	-
2002/03	60.0	30.0	-
2003/04	40.0	30.0	-
2004/05	40.0	30.0	-
2005/06	40.0	30.0	-
2006/07	40.0	20.0	-
2007/08	40.0	20.0	-
2008/09	40.0	20.0	-
2009/10	Stopped	120.0	Approved
2010/11	-	120.0	160.0
2011/12	-	120.0	155.0
2012/13	-	120.0	150.0
2013/14	-	80.0	150.0
2014/15	-	80.0	150.0

We'll return to this later in NPV split analyses

Look Around – Industry Standards/Comparables

Comparable Transactions

- Probably the most important valuation method for academic licensing.
- Sources of Comparable Transactions
  - Internal database
  - Published surveys
  - Public announcements
  - Word of mouth
  - Litigation
  - Required disclosure

Internal Database

- Licenses previously done by your organization
- Trends over time

Published Surveys

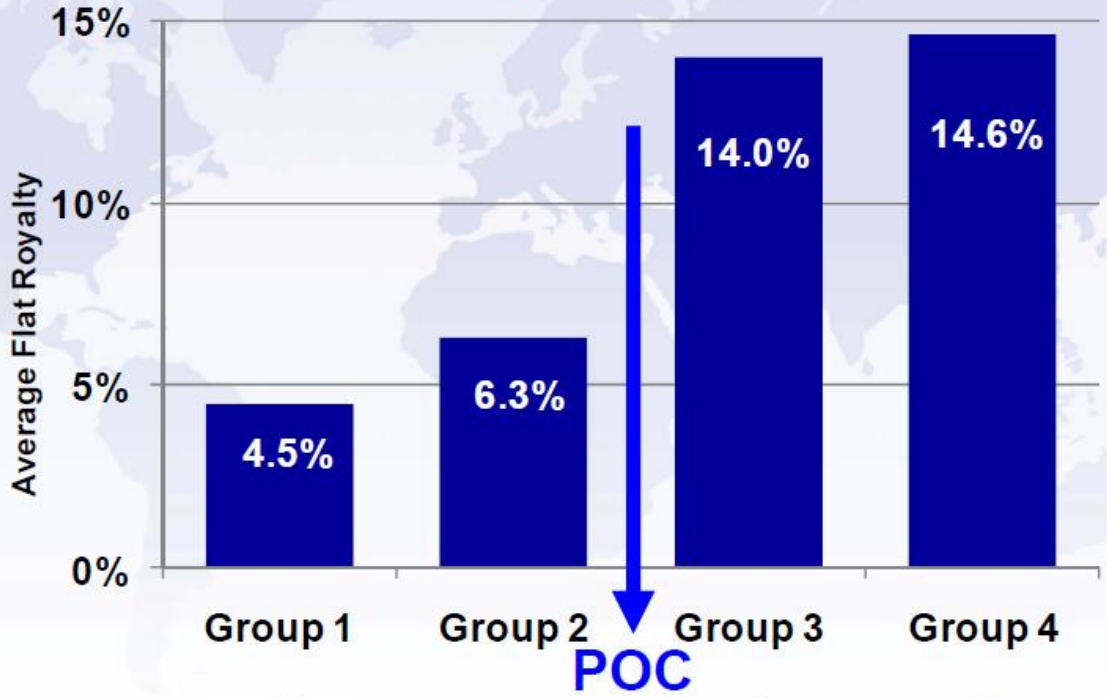
- Relatively few in number
- Most are really old
- Three good current surveys:
  - LES
    - BioPharmaceutical Royalty Rates and Deal Terms Survey (2008, 2009, 2012, 2014, 2016, 2018, 2021)
    - High Tech Survey (2011, 2014, 2017, 2021)
    - Chemicals, Energy, Environmental and Materials (CEEM) Survey (2010)

LES BioPharmaceutical Royalty Rates and Deal Terms Survey – 2016

- 165 responses, 117 complete and used
- Oncology, CNS and infectious diseases most prevalent
- 84% were exclusive
- 87% included U.S. and 80% were global
- 55% pre-IND
  - Very useful for universities
- 68% had expected peak sales <$500 million
- Royalty structure
  - 62% fixed royalties
  - 27% tiered royalties
  - 9% no royalty
    - 1% profit share
    - 8% no royalties

Flat Royalties
Average Royalty by Stage of Development

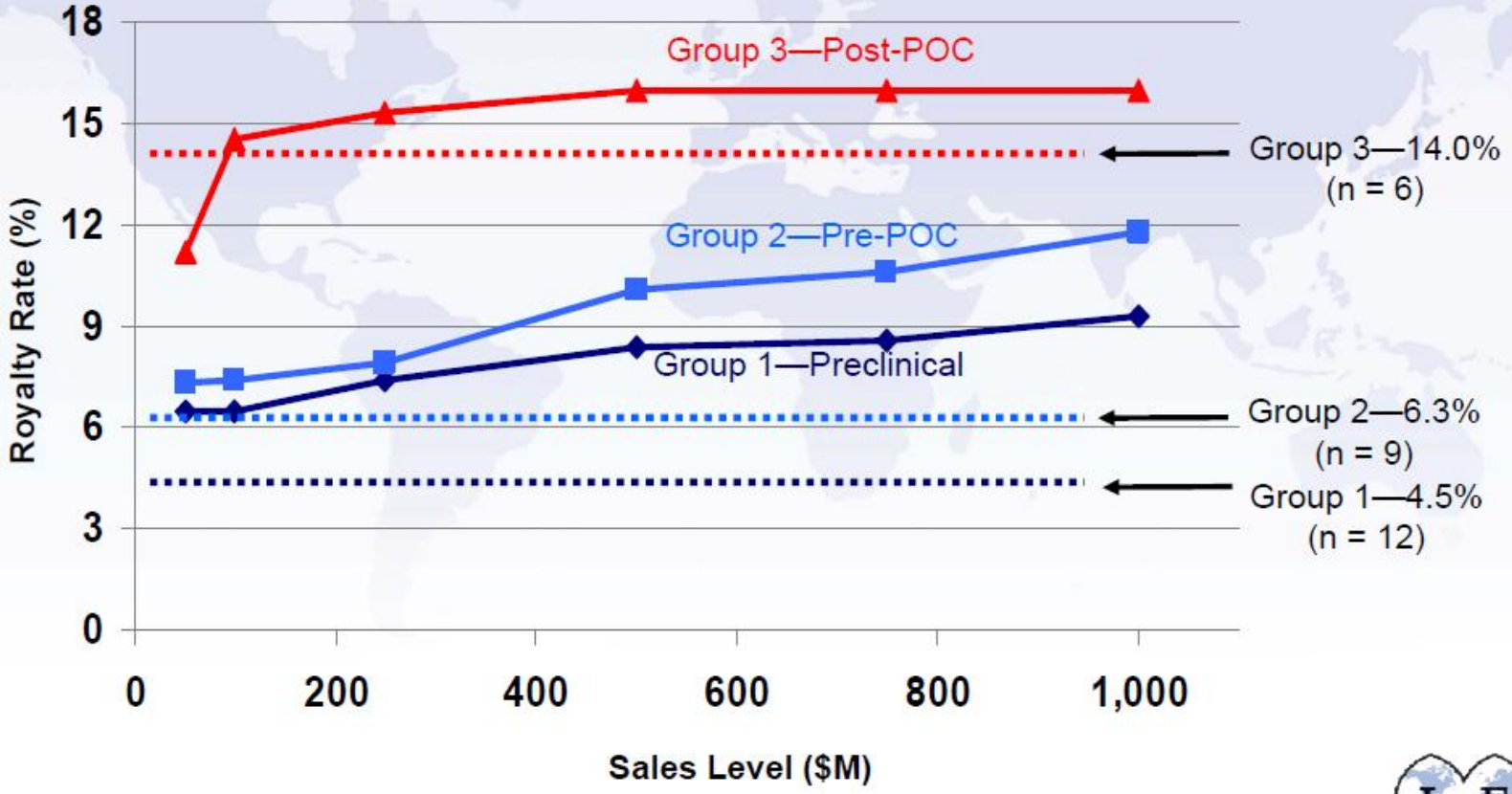
Royalty level increased with stage of development.



	Group 1	Group 2	Group 3	Group 4
No. of deals	27	6	5	7
Median	5%	5%	16%	15%
Min	1%	2%	3%	7%
Max	10%	20%	20%	30%

Flat vs. Tiered Royalties
Stage of Development

Within groups, mean flat royalty levels were below the values for tiered royalties.



AUTM

- TransACT
- Launched 2015
  - Academic deals
    - “Display or Pay”
      - Contribute a number of deals depending on your research volume
- Has severe limitations
  - The subject matter must be selected from a pick-list
    - All healthcare is the same code
      - E.g., a search for small molecule drugs yields ~80 hits
        - 26 have royalty rates
  - Can’t download all the data into a spreadsheet for analysis
    - One by one
- May be most useful for non-healthcare

Required Disclosure

- Contained in SEC filings
- Company must be public or have filed to go public
- Contained in **exhibits** to the S1 (IPO), 10K (Annual Report), 10Q (Quarterly Report) or 8K (Material Event)
- Only for “Material” transactions
  - 10% of sales, or
  - 5% of assets
- Can redact commercially sensitive information from public disclosure
  - Redaction has increased since transition to electronic filing
  - Redaction only good for 5 years
    - Some databases good at going back and getting the unredacted data

Steps

- Identify comparable transactions that would be helpful models
- Determine if the agreement has been filed with SEC
- Find it!

Accessing SEC Filings Yourself

- SEC EDGAR system
  - www.sec.gov/edgar/searchedgar/companysearch.html
  - Much more user friendly now
  - Companies phased in progressively:
    - Largest January 1994
    - Smallest May 1996
  - For pre-Edgar transactions, early10K will show when/whether it was filed

Some Databases to Find Comparables

Technology	
RoyaltySource	royaltysource.com/
RoyaltyStat	www.royaltystat.com/
Business Valuation Resources	www.bvresources.com/

Life Sciences	
Clarivate (former ReCap)	www.cortellis.com/intelligence
BioScience Advisors	www.biosciadvisors.com
IQVIA (former PharmaDeals)	www.pharmadeals.net/
Strategic Transactions (Windhover)	www.elsevierbi.com/deals

- All charge – either per agreement ($35) or an annual subscription
- Some let you identify agreements before you have to pay
  - Find them yourself through the SEC

Search Strategies

- No Cost
  - Search using Strategic Transactions (Life Sciences)
    - Physical sciences one has gone out of business
  - Find agreements using SEC
- High Cost Life Sciences
  - Search and get agreements using Clarivate or BioScience Advisors
- Alternative
  - Use a consultant for a specific technology
  - $2-3,000

Example

- siRNA
- Tools:
  - Clarivate
  - EDGAR

Cortellis

Clarivate Analytics

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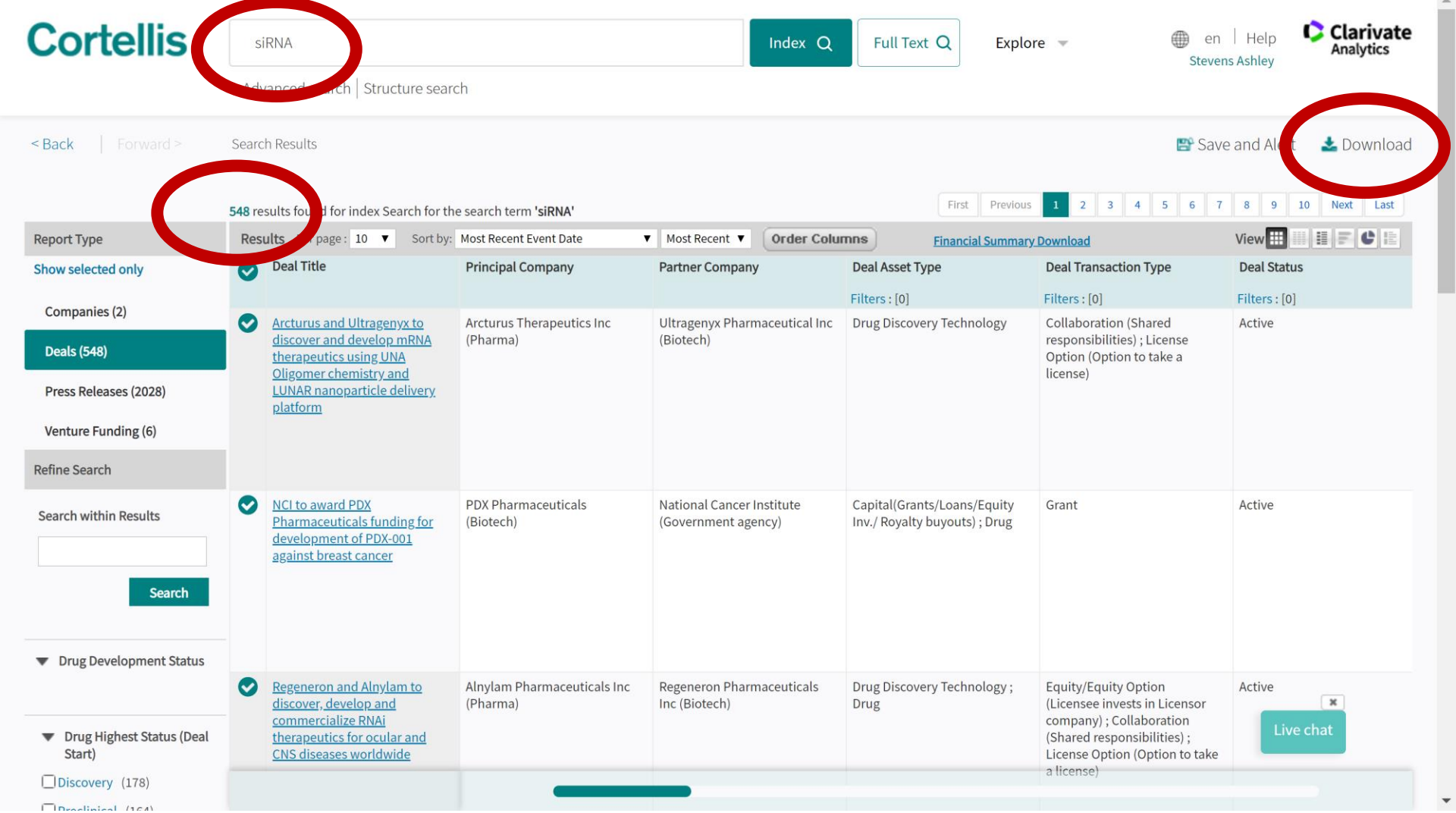


Deal Title	Principal Company	Principal Company Typ
Arcturus and Ultragenyx to discover and develop mRNA therapeutics using UNA	Arcturus Therapeutics Inc	Pharma
NCI to award PDX Pharmaceuticals funding for development of PDX-001 against breast	PDX Pharmaceuticals	Biotech
Regeneron and Alnylam to discover, develop and commercialize RNAi therapeutics for	Alnylam Pharmaceuticals Inc	Pharma
Janssen to develop and commercialize Arrowhead's ARO-HBV, with an option to	Arrowhead Pharmaceuticals Inc	Pharma
Nitto Denko and Osaka International Cancer Institute to develop new nucleic acid	Nitto Denko Corp	Other (non industrial)
Genzyme to develop Alnylam's RNAi therapeutics worldwide, excluding North	Alnylam Pharmaceuticals Inc	Pharma
Thea to develop and commercialize OliX's OLX-301A against age-related macular	OliX Pharmaceuticals Inc	Pharma
Karolinska Institute to conduct clinical trial for Alnylam Pharmaceuticals' givosiran for acute	Karolinska Institutet	Academic
Medison Pharma to commercialize Alnylam's RNAi therapeutics for rare diseases in Israel	Alnylam Pharmaceuticals Inc	Pharma
Covance to provide OliX with GLP toxicology study services for OLX-10020 against GA	Covance Inc	Biotech
OliX Pharmaceuticals and University of Virginia School of Medicine to conduct	University of Virginia School of Medicine	Academic
Dicerna and Boehringer to discover and develop GalXC RNAi therapeutics for NASH	Dicerna Pharmaceuticals Inc	Pharma
Aro Biotherapeutics to develop and commercialize Janssen's Centyrin protein	Janssen Pharmaceuticals Inc	Pharma

Results

- 36 fields, covering:
  - Partners
  - Technology
  - Legal components of the deal
  - Financial terms
  - Actual documents
  - Stage of development

Results

- 548 deals
  - 109 had some financial information
  - 25 had royalty information
- 164 PSRI
  - 122 academic
  - 13 government agency
  - 29 non-profit
    - 41 had some financial information
    - 6 had royalty information, 1% - 10%
    - 6 had license agreement
      - 4 unredacted
      - 2 redacted

Results

Principal Company	Partner Company	Therapy Area	Indications	Drugs Status	Date	Total Value	Upfr.	Milest.	Royalty Rate (%)
Mayo Clinic	Alnylam	CNS	Parkinsons	Preclinical	10/01/03	3.97		3.75	1.00
Stanford	Alnylam	Unknown	Unidentified	Preclinical	09/17/03	0.77		0.73	2.00
U. of Penns.	Acuity	Ocular	AMD	Preclinical	03/31/03	1.00		0.95	2.00
U. of Illinois	Acuity	Ocular	Ocular	Discovery	08/01/06	2.50	0.03	2.45	3.00
UMass Med. Sch.	CytRx	Var,	Onc., NIDDM; Obesity	Discovery	04/15/03	6.50	0.08	6.3	10.00
UMass Med. Sch.	CytRx	CNS	ALS	Discovery	04/15/03	34.13	0.01	1.57	10.00

Old System

- A lot has been lost as the ReCap database has been repeatedly sold and reformatted
  - The unredacted copy of the agreement is available
    - Was in ReCap and Thomson Reuters versions
  - Only redacted version of the Acuity-U. of IL deal is available in Clarivate
  - Following is from the Thomson Reuters days
- I've changed my subscription to the new database created by Mark Edwards, BioScience Advisors
  - Creator of ReCap

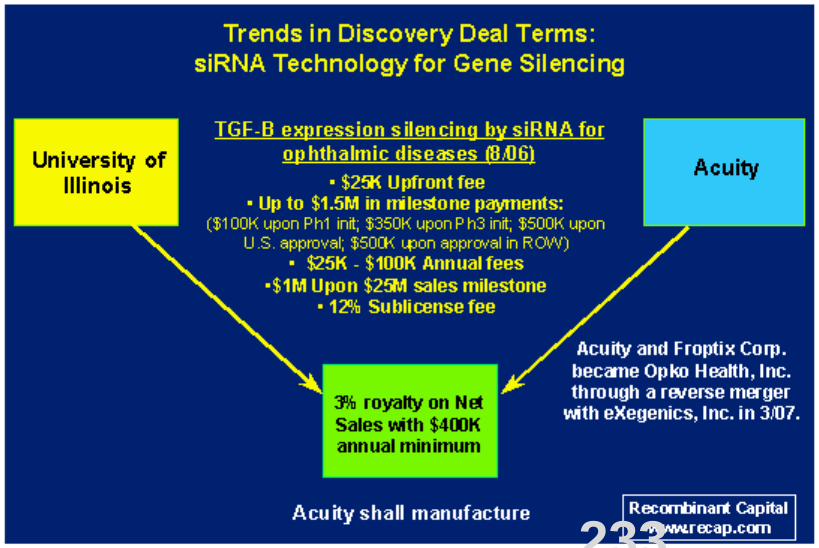
Alliance Summary

R&D Company:	University of Illinois	**R&D Parent:**	
Client Company:	Acuity Pharmaceuticals	**Client Parent:**	Opko Health

Date: 08/2006
Parties: University / Biotech
Type: License
Subject:
TGF-B expression silencing by siRNA for ophthalmic diseases

Size:	$ 2.5 M	**Therapeutic Area:**	Ophthalmic Broad Focus Ophthalmic
Equity:	$ 0 M	**Technology:**	Gene Expression, Oligonucleotides - Ribozymes
Max. Royalty:	3 %	**Stage (at signing):**	Discovery

SNAPSHOT:



LICENSE

Exclusivity:	Exclusive	**Licensed Territory:**	Worldwide

Contract Analysis

R&D Company:	University of Illinois	**R&D Parent:**	
Client Company:	Acuity Pharmaceuticals	**Client Parent:**	Opko Health
Agreement Date:	08/2006		
Alliance Summary:	Open parent Alliance Summary		

Related Contracts:

Agreement	Contract type	Contract date	pdf	Refile
University of Illinois / Acuity Pharmaceuticals (08/2006)	License	08/2006		

I. Research & Development

A. Scope of the Agreement
On 8/3/2006 ("Effective Date"), the University of Illinois (the "University") and Acuity Pharmaceuticals, Inc. ("Acuity") entered into a license agreement ("Agreement") to develop treatments for ophthalmic diseases based on TGF-beta receptor expression silencing by siRNA. [On 3/27/2007, Acuity and Froptix Corporation ("Froptix"), both privately owned, became Opko Health, Inc. ("Opko") through a reverse merger with publicly-traded eXegenics, Inc. (see Separate Deal Background -- Opko / Acuity, Froptix 3/07).]

B. Research Period
N/A

C. Cost Sharing & Reimbursement Basis
N/A

D. Upfront Payment
Acuity shall pay the University a $25K license fee within 3 business days of the Effective Date.

E. Benchmark Amounts
Acuity shall pay the University the following one-time milestone payments upon the first achievement of the following development milestone events: (1) $100K upon the initiation of phase I; (2) $350K upon the initiation of phase III; (3) $500K upon approval in the U.S.; and (4) $500K upon approval outside the U.S. Acuity shall pay the University a sales milestone of $1M upon reaching the first $25M in commercial sales of the Licensed Product (see Section II.A.).

F. Technology Acquisition Fees
N/A

G. Payment Schedule
N/A

H. Budgets
No

I. Reimbursement Start Date:
N/A

J. Regulatory Filings
All by Acuity.

K. Special Capital Requirements
None

L. Patent Ownership
The University shall not be obliged to provide Acuity or its sublicensees with any updates to the Technical Information. "Technology" shall mean the Inventions, Licensed Patents, and Technical Information, collectively. "Inventions" shall mean all devices, machines, methods, processes, manufactures, compositions of matter and uses, and Technical Information, contained in the disclosure entitled "CW081 Silencing of TGF-beta Receptor Expression by siRNA." "Licensed Patents" shall mean the following patents and applications owned by the University including any continuations, reissues, or foreign

Contract

R&D:	University of Illinois	**R&D Parent:**	
Client:	Acuity Pharmaceuticals	**Client Parent:**	Opko Health
Parties:	University / Biotech	**Subject:**	TGF-B expression silencing by siRNA for ophthalmic diseases
Alliance Summary:	Open parent Alliance Summary		

Alliance Type:	License	**Date:**	08/2006
		Revision:	

Contract Type:	License	**Filing Date:**	08/2006

CONTENT: EX-10.8 8 g06337exv10w8.htm EX-10.8 TECHNOLOGY LICENSE AGREEMENT

EXHIBIT 10.8

TECHNOLOGY LICENSE AGREEMENT

License Agreement ("**Agreement**"), effective as of August 3, 2006 between THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, (the "**University**"), and ACUITY PHARMACEUTICALS, INC., a Delaware corporation, having its principle place of business at 3701 Market Street, Philadelphia, PA, 19104 ("**Licensee**" or "**Acuity**").

Preliminary Statement

University holds certain rights to the Technology described below and desires to have the Technology commercialized. Licensee wishes to obtain the right to use the Technology for commercial purposes. Therefore, in consideration of the mutual obligations set forth below and other valuable consideration, the receipt and sufficiency of which is hereby acknowledged, University and Licensee agree as follows.

ARTICLE I
DEFINITIONS

The following capitalized terms are used in this Agreement with the following meanings:

1.1. "**Effective Date**" means August 3, 2006.

1.2. **"FDA"** means the United States Food and Drug Administration, or any successor thereto.

1.3. "**IND**" means an "investigational new drug application" as defined by the United States Food, Drug, and Cosmetic Act, as amended (the "Act"), and applicable FDA rules and regulations or a foreign equivalent.

1.4. **"Inventions"** means all devices, machines, methods, processes, manufactures, compositions of matter and uses, and Technical Information, contained in the disclosure entitled "CW081 Silencing of TGF ß Receptor Expression by SiRNA."

1.5. "**Licensed Field**" means the inhibition of and treatment of ophthalmic disease.

1.6. "**Licensed Patents**" means (a) the patents and patent applications listed on Schedule 1 and any continuations, divisionals, reissues, renewals, re-examinations, foreign counterparts, or substitutions of or to the above.

1.7. "**Licensed Product**" means any product or process or license for information, in the Field of Use, that is distributed by Licensee that is covered by any of the University's rights in the Technology.

1.8. **"NDA"** means a "new drug application," as defined in the Act and applicable FDA rules and regulations, including an application of the type described in section 505(b)(2) of the Act.

obligation to provide Licensee or any Sublicensee with any updates of or additional Technical Information owned, controlled or in the possession of any of them.

ARTICLE III
PAYMENTS

3.1. **Royalties and Reimbursements**. For the licenses granted in Section 2.1 of this Agreement, Licensee shall:

(a) within three (3) business days of the execution of this Agreement, pay University a non-refundable licensing fee in the amount of $25,000;

(b) within thirty (30) days of the first and second anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $25,000;

(c) within thirty (30) days of the third anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $50,000;

(d) within thirty (30) days of the fourth anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $50,000;

(e) within thirty (30) days of the fifth anniversary of the Effective Date and each subsequent anniversary thereafter until the Licensee receives NDA approval on its first Licensed Product, pay University an annual non-refundable licensing fee in the amount of $100,000;

(f) pay University a Royalty equal to three percent (3%) of Net Sales of Licensed Products sold, leased, rented, licensed or otherwise distributed by Licensee during the term of this Agreement, if any. If no valid claim of any issued patent among the Licensed Patents covers the Licensed Products in a country of the Territory, then the royalties shall be reduced to one and one-half percent (1.5%) of Net Sales of Licensed Products sold, leased, rented, licensed or otherwise distributed by Licensee in such country of the Territory.

3.2. **Milestones and Milestone Payments**. Licensee agrees to make the milestone payments to University as set forth below (the "**Milestone Payments**") within forty-five (45) days after the occurrence of each event set forth on such Schedule.

Milestone		**Payment**
First Phase I Clinical Trial initiated	$	100,000
First Phase III Clinical Trial initiated	$	350,000
First NDA Approval in the U.S	$	500,000
First NDA Equivalent Approval outside of US	$	500,000
Upon first $25,000,000 of commercial sales of any Licensed Products	$	1,000,000

Each of the foregoing payments shall be made only once. Thereafter, no additional Milestone Payments shall be due or payable by Licensee for License Products.

3.3. **Calculations and Payment of Royalties.**

(a) Royalties shall be paid in quarterly increments (the "Royalty Period"). Royalties shall be calculated for each Royalty Period as of the last day of each such Royalty Period. Payment of Royalties with respect to each Royalty Period shall be due within sixty (60) days after the end of Royalty Period, beginning with the earlier of (i) the Royalty Period in which the first sale of a Licensed Product occurs, or (ii) the Royalty Period for which Annual Minimum Royalties are due.

(b) Within sixty (60) days of the end of each Royalty Period (whether or not Royalties are due), Licensee shall deliver to University a true and complete accounting of sales or distributions of any Licensed Product and revenues from those sales by Licensee and its Sublicensees for each country of sales origin during such Royalty Period and deductions taken, with a separate accounting for each Licensed Product of sales and receipts by country, and a detailed calculation of the Royalty payment due University for such Royalty Period, in each case in form and

Search Results

Save Search Modify Search New Search

8 results.
CRITERIA: ([Company] CONTAINS "Acuity Pharmaceuticals")

	Parties	Date	Type	Size	Upfront	Total Milestone	Royalty	Subject
1	Acuity Pharmaceuticals, Froptix / Opko Health	03/2007	Acq, Mrg					Reverse merger with eXegenics to form Opko Health
2	University of Illinois / Acuity Pharmaceuticals	08/2006	L	$2.5	$0.0	$1.5	3.0%	TGF-B silencing by siRNA for ophthalmic diseases
3	ZaBeCor / Acuity Pharmaceuticals	04/2006	L, O					Excellair anti-Inflammatory siRNA for Ophthamalic uses
4	Pathogenics / Acuity Pharmaceuticals	04/2006	L	$6.5	$0.1	$6.4	6.0%	N-chlorotaurine For Ophthalmic Use
5	Intradigm / Acuity Pharmaceuticals	06/2005	CoD, Col, L, E	$5.6	$0.5	$5.1	8.0%	siRNA for topical delivery to the eye
6	Ocimum Biosolutions / Acuity Pharmaceuticals	08/2004	L					Genchek-Comprehensive Sequence Analysis Tool
7	University of Pennsylvania / Acuity Pharmaceuticals	03/2003	L, E	$1.0		$1.0	8.0%	RNA interference technologies (Gewirtz)
8	University of Pennsylvania / Acuity Pharmaceuticals	03/2003	L, E	$1.0		$1.0	2.0%	RNA interference technologies (Reich/Tolentinio)

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State location: FL | State of Inc.: **DE** | Fiscal Year End: 1231
formerly: CYTOCLONAL PHARMACEUTICS INC /DE (filings through 2001-06-04)
formerly: EXEGENICS INC (filings through 2007-06-13)
formerly: eXegenics Inc (filings through 2007-06-13)
(Assistant Director Office: 1)
Get **insider transactions** for this **issuer**.
Get **insider transactions** for this **reporting owner**.

Business
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MIAMI FL
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Items 1 - 40 RSS Feed

Filings	Format	Description
8-K	Documents	Current report, item 5.02 Acc-no: 0000944809-19-000043 (34 Act) Size: 37 KB
8-K	Documents	Current report, items 5.03, 5.07, 7.01, and 9.01 Acc-no: 0000944809-19-000041 (34 Act) Size: 89 KB
SC 13D	Documents	General statement of acquisition of beneficial ownership Acc-no: 0001193125-19-171306 Size: 124 KB
SC 13D	Documents	General statement of acquisition of beneficial ownership Acc-no: 0001193125-19-171303 Size: 117 KB
SC 13D	Documents	General statement of acquisition of beneficial ownership Acc-no: 0001193125-19-171298 Size: 113 KB
SC 13D	Documents	General statement of acquisition of beneficial ownership Acc-no: 0001193125-19-171297 Size: 116 KB
8-K	Documents	Current report, item 7.01 Acc-no: 0000944809-19-000039 (34 Act) Size: 30 KB
8-K	Documents	Current report, item 8.01 Acc-no: 0000944809-19-000036 (34 Act) Size: 28 KB

EDGAR Search Results

Opko Health, Inc. CIK#: 0000944809 (see all company filings)

SIC: 2834 - PHARMACEUTICAL PREPARATIONS
State location: FL | State of Inc.: **DE** | Fiscal Year End: 1231
formerly: CYTOCLONAL PHARMACEUTICS INC /DE (filings through 2001-06-04)
formerly: EXEGENICS INC (filings through 2007-06-13)
formerly: eXegenics Inc (filings through 2007-06-13)
(Assistant Director Office: 1)
Get **insider transactions** for this **issuer**.
Get **insider transactions** for this **reporting owner**.

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Items 1 - 40 RSS Feed

Filings	Format	Description	Filing Date
8-K	Documents	Current report, items 1.01, 3.02, and 9.01 Acc-no: 0001144204-07-065847 (34 Act) Size: 52 KB	2007-12-05
8-K	Documents	Current report, items 1.01, 2.01, and 9.01 Acc-no: 0001144204-07-064922 (34 Act) Size: 49 KB	2007-11-29
8-K	Documents	Current report, items 5.02 and 8.01 Acc-no: 0000950144-07-008821 (34 Act) Size: 12 KB	2007-09-25
8-K	Documents	Current report, items 1.01, 5.02, and 9.01 Acc-no: 0000950144-07-004724 (34 Act) Size: 66 KB	2007-05-11
8-K	Documents	Current report, item 1.01 Acc-no: 0000950144-07-003524 (34 Act) Size: 11 KB	2007-04-18
8-K	Documents	Current report, items 4.01, 5.02, and 9.01 Acc-no: 0000950144-07-003401 (34 Act) Size: 47 KB	2007-04-13
8-K	Documents	Current report, items 1.01, 2.01, 3.02, 5.01, 5.02, 5.06, and 9.01 Acc-no: 0000950144-07-002945 (34 Act) Size: 2 MB	2007-04-02
8-K	Documents	Current report, items 3.03 and 9.01 Acc-no: 0001144204-07-014826 (34 Act) Size: 44 KB	
8-K	Documents	Current report, items 3.02, 5.01, 5.02, 8.01, and 9.01	2007-02-09

Form 8-K - *Current report:*

Filing Date
2007-04-02
Accepted
2007-04-02 07:13:22
Documents
22

Period of Report
2007-03-27

Items
Item 1.01: Entry into a Material Definitive Agreement
Item 2.01: Completion of Acquisition or Disposition of Assets
Item 3.02: Unregistered Sales of Equity Securities
Item 5.01: Changes in Control of Registrant
Item 5.02: Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers: Compensatory Arrangements of Certain Officers
Item 5.06: Change in Shell Company Status
Item 9.01: Financial Statements and Exhibits

Document Format Files

Seq	Description	Document	Type	Size
1	EXEGENICS, INC.	g06337e8vk.htm	8-K	889948
2	EX-2.1 MERGER AGREEMENT & PLAN OF REORGANIZATION	g06337exv2w1.htm	EX-2.1	294509
3	EX-4.1 FORM OF COMMON STOCK WARRANT	g06337exv4w1.htm	EX-4.1	33331
4	EX-4.2 FORM OF SERIES C PREFERRED STOCK WARRANT	g06337exv4w2.htm	EX-4.2	32645
5	EX-10.1 FORM OF LOCK-UP AGREEMENT	g06337exv10w1.htm	EX-10.1	9947
6	EX-10.2 CREDIT AGREEMENT	g06337exv10w2.htm	EX-10.2	86185
7	EX-10.3 AMENDED & RESTATED VENTURE LOAN AGREEMENT	g06337exv10w3.htm	EX-10.3	210041
8	EX-10.8 TECHNOLOGY LICENSE AGREEMENT	g06337exv10w8.htm	EX-10.8	96413
9	EX-10.9 LICENSE AGREEMENT	g06337exv10w9.htm	EX-10.9	87487
10	EX-10.10 AMENDMENT NO. 1 TO LICENSE AGREEMENT	g06337exv10w10.htm	EX-10.10	8079
11	EX-10.11 AMENDMENT NO. 2 TO LICENSE AGREEMENT	g06337exv10w11.htm	EX-10.11	7548
12	EX-10.12 LICENSE AND COLLABORATION AGREEMENT	g06337exv10w12.htm	EX-10.12	127884
13	EX-10.13 UNIV. OF PENN. LICENSE AGREEMENT	g06337exv10w13.htm	EX-10.13	66692
14	EX-10.14 UNIV. OF PENN LICENSE AGREEMENT	g06337exv10w14.htm	EX-10.14	66493
15	EX-10.15 1ST AMENDMENT TO UPENN LICENSE AGREEMENT	g06337exv10w15.htm	EX-10.15	12050
16	EX-10.16 1ST AMENDMENT TO UPENN LICENSE AGREEMENT	g06337exv10w16.htm	EX-10.16	10147
17	EX-10.17 AMENDED RESTATED SUBORDINATION AGREEMENT	g06337exv10w17.htm	EX-10.17	25982
18	EX-10.18 REICH EMPLOYMENT LETTER	g06337exv10w18.htm	EX-10.18	25379
19	EX-10.19 PFOST EMPLOYMENT AGREEMENT	g06337exv10w19.htm	EX-10.19	51353
20	EX-99.1 PRESS RELEASE	g06337exv99w1.htm	EX-99.1	9676
21	GRAPHIC	g06337g0633701.gif	GRAPHIC	7428
22	GRAPHIC	g06337g0633702.gif	GRAPHIC	1541
	Complete submission text file	0000950144-07-002945.txt		216658

eXegenics Inc (Filer) CIK: 0000944809 (see all company filings)

IRS No.: **752402409** | State of Incorp.: **DE** | Fiscal Year End: **1231**
Type: **8-K** | Act: **34** | File No.: **000-26648** | Film No.: **07735592**

Business Address
1250 PITTSFORD-VICTOR ROAD
BUILDING 200, SUITE 280

EXHIBIT 10.8

TECHNOLOGY LICENSE AGREEMENT

License Agreement ("**Agreement**"), effective as of August 3, 2006 between THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, (the "**University**"), and ACUITY PHARMACEUTICALS, INC., a Delaware corporation, having its principle place of business at 3701 Market Street, Philadelphia, PA, 19104 ("**Licensee**" or "**Acuity**").

Preliminary Statement

University holds certain rights to the Technology described below and desires to have the Technology commercialized. Licensee wishes to obtain the right to use the Technology for commercial purposes. Therefore, in consideration of the mutual obligations set forth below and other valuable consideration, the receipt and sufficiency of which is hereby acknowledged, University and Licensee agree as follows.

ARTICLE I
DEFINITIONS

The following capitalized terms are used in this Agreement with the following meanings:

1.1. "**Effective Date**" means August 3, 2006.

1.2. **"FDA"** means the United States Food and Drug Administration, or any successor thereto.

1.3. "**IND**" means an "investigational new drug application" as defined by the United States Food, Drug, and Cosmetic Act, as amended (the "Act"), and applicable FDA rules and regulations or a foreign equivalent.

1.4. **"Inventions"** means all devices, machines, methods, processes, manufactures, compositions of matter and uses, and Technical Information, contained in the disclosure entitled "CW081 Silencing of TGF ß Receptor Expression by SiRNA."

1.5. "**Licensed Field**" means the inhibition of and treatment of ophthalmic disease.

1.6. "**Licensed Patents**" means (a) the patents and patent applications listed on Schedule 1 and any continuations, divisionals, reissues, renewals, re-examinations, foreign counterparts, or substitutions of or to the above.

1.7. "**Licensed Product**" means any product or process or license for information, in the Field of Use, that is distributed by Licensee that is covered by any of the University's rights in the Technology.

1.8. **"NDA"** means a "new drug application," as defined in the Act and applicable FDA rules and regulations, including an application of the type described in section 505(b)(2) of the Act.

1.9. "**Net Sales**" means the total gross proceeds to Licensee on sales and any other distributions of Licensed Products to third parties, less deductions for the following to the extent actually paid with respect to such sales or distributions:

(a) Customary rebates;

3.1. **Royalties and Reimbursements**. For the licenses granted in Section 2.1 of this Agreement, Licensee shall:

(a) within three (3) business days of the execution of this Agreement, pay University a non-refundable licensing fee in the amount of $25,000;

(b) within thirty (30) days of the first and second anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $25,000;

(c) within thirty (30) days of the third anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $50,000;

(d) within thirty (30) days of the fourth anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $50,000;

(e) within thirty (30) days of the fifth anniversary of the Effective Date and each subsequent anniversary thereafter until the Licensee receives NDA approval on its first Licensed Product, pay University an annual non-refundable licensing fee in the amount of $100,000;

(f) pay University a Royalty equal to three percent (3%) of Net Sales of Licensed Products sold, leased, rented, licensed or otherwise distributed by Licensee during the term of this Agreement, if any. If no valid claim of any issued patent among the Licensed Patents covers the Licensed Products in a country of the Territory, then the royalties shall be reduced to one and one-half percent (1.5%) of Net Sales of Licensed Products sold, leased, rented, licensed or otherwise distributed by Licensee in such country of the Territory.

3.2. **Milestones and Milestone Payments**. Licensee agrees to make the milestone payments to University as set forth below (the "**Milestone Payments**") within forty-five (45) days after the occurrence of each event set forth on such Schedule.

Milestone	Payment
First Phase I Clinical Trial initiated	$ 100,000
First Phase III Clinical Trial initiated	$ 350,000
First NDA Approval in the U.S	$ 500,000
First NDA Equivalent Approval outside of US	$ 500,000
Upon first $25,000,000 of commercial sales of any Licensed Products	$1,000,000

Each of the foregoing payments shall be made only once. Thereafter, no additional Milestone Payments shall be due or payable by Licensee for License Products.

3.3. **Calculations and Payment of Royalties.**

(a) Royalties shall be paid in quarterly increments (the "Royalty Period"). Royalties shall be calculated for each Royalty Period as of the last day of each such Royalty Period. Payment of Royalties with respect to each Royalty Period shall be due within sixty (60) days after the end of Royalty Period, beginning with the earlier of (i) the Royalty Period in which the first sale of a Licensed Product occurs, or (ii) the Royalty Period for which Annual Minimum Royalties are due.

(b) Within sixty (60) days of the end of each Royalty Period (whether or not Royalties are due), Licensee shall deliver to University a true and complete accounting of sales or distributions of any Licensed Product and revenues from those sales by Licensee and its Sublicensees for each country of sales origin during such Royalty Period and deductions taken, with a separate accounting for each Licensed Product of sales and receipts by country, and a detailed calculation of the Royalty payment due University for such Royalty Period, in each case in form and substance as set forth on Exhibit A attached to this Agreement. If no sales of Licensed Products were made or other payments due in such Royalty Period, then Licensee's statement shall so state.

(c) Each Annual Minimum Royalty payment shall be accompanied by a calculation of the Annual Minimum Royalty such that University can verify the amount of the payment.

3.4. **Royalty stacking and combination products**: The royalty rate will not diminish for combination products or stacking royalties.

3.5. **Annual Minimum Payments**. Beginning one year after the Licensee or any Sublicensee receives NDA approval on its first Licensed Product, it the total payments actually paid to University payments (including any payments

Company Valuation

- Most recent 10Q to get number of shares outstanding
- Share prices:
  - www.nasdaq.com/

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2019.

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____.

Commission file number 001-33528

OPKO Health, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**75-2402409**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

4400 Biscayne Blvd.
Miami, FL 33137
(Address of Principal Executive Offices) (Zip Code)

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ YES ☐ NO

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ YES ☐ NO

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company"
(in Rule 12b-2 of the Exchange Act) (Check one):

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐
		Emerging growth company	☐

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If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): ☐ YES ☒ NO

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock	QPK	NASDAQ Global Select Market

As of April 24, 2019, the registrant had 615,601,045 shares of Common Stock outstanding.

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U.S. Stock Quotes, Charts, and Research

Find stock quotes, interactive charts, historical information, company news and stock analysis on all public companies in the U.S..

1 Get A Stock Quote: Enter up to 25 symbols

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Opko

2 Click a link below to filter your results

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- Ownership Summary

ADDITIONAL STOCK RESEARCH

View Security List	Download Security List
NASDAQ	NASDAQ (406KB)
Amex	Amex (51KB)
NYSE	NYSE (412KB)

U.S. Symbol Changes

OPKO Health, Inc. Common Stock (OPK) Quote & Summary Data

OPK $2.37* **0.04 ↓ 1.66%**

*Delayed - data as of Jul. 3, 2019 - Find a broker to begin trading OPK now

Exchange:NASDAQ
Industry: Health Care
Community Rating: Bullish

Edit Symbol List
Symbol Lookup

OPK | SGMO | CLLS | S | CRSP | EDIT | NTLA | NDAQ

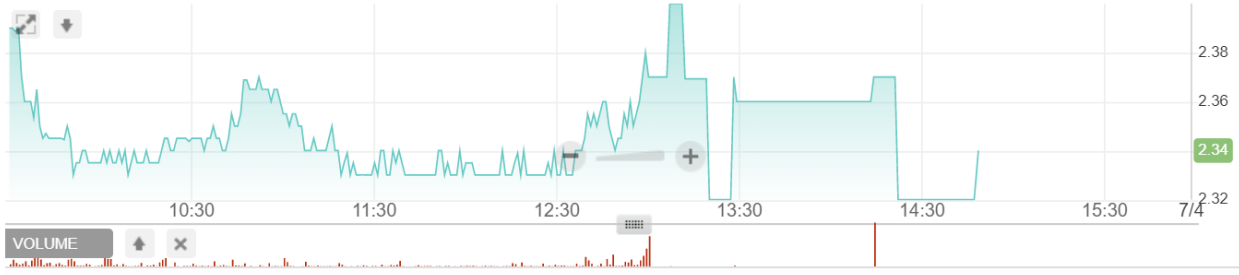
Save Stocks | Refresh

SYMBOL LIST VIEWS
FlashQuotes
InfoQuotes
STOCK DETAILS
Summary Quote
Real-Time Quote
After Hours Quote
Pre-market Quote
Historical Quote
Option Chain
CHARTS
Basic Chart
Interactive Chart
COMPANY NEWS
Company Headlines
Press Releases
Market Stream
STOCK ANALYSIS
Analyst Research
Guru Analysis
Stock Report

Key Stock Data

Best Bid / Ask	N/A / N/A	P/E Ratio	NE
1 Year Target	4.5	Forward P/E (1y)	NE
Today's High / Low	$ 2.41 / $ 2.33	Earnings Per Share (EPS)	$ -0.33
Share Volume	2,370,522	Annualized Dividend	N/A
50 Day Avg. Daily Volume	4,944,550	Ex Dividend Date	N/A
Previous Close	$ 2.41	Dividend Payment Date	N/A
52 Week High / Low	$ 6.40 / $ 1.73	Current Yield	0 %
Market Cap	1,458,974,477	Beta	2.52

Intraday Chart



1D | 5D | 1m | 3m | 6m | 1y

More OPK Charting >

Upcoming Earnin

Company	Expect
FGP	Jun 10,
THO	Jun 10,
HDS	Jun 11,
HRB	Jun 11,
CHS	Jun 11,
AVGO	Jun 13,
TUFN	Jun 13,
CPST	Jun 11,

See Also

1 | Best Stocks To
2 | IPO Investment
3 | #1 Penny Stock
4 | Ipo Stocks To W

CONSENSUS RE

OPK $2.37* 0.04 ▼ 1.66%

*Delayed - data as of Jul. 3, 2019 - Find a broker to begin trading OPK now

Community Rating: Bullish

Edit Symbol List
Symbol Lookup

OPK | SGMO | CLLS | S | CRSP | EDIT | NTLA | NDAQ

Save Stocks

SYMBOL LIST VIEWS
FlashQuotes
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Summary Quote
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After Hours Quote
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Historical Quote
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STOCK ANALYSIS
Analyst Research
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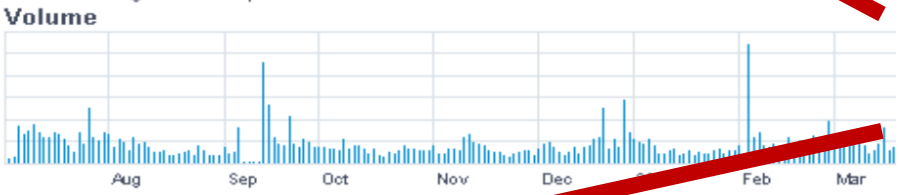
Competitors
Stock Consultant
Stock Comparison
FUNDAMENTALS
Call Transcripts



The chart comes up showing a I year history. Pick 10 years and hit “Go”.

Time Frame: 1 Year

Chart Display:

Chart Type:
OHLC | Bar | Line | Candlestick | Mountain

Indicators:
Splits | Earnings *

Moving Average:
None | 20 Day | 50 Day | 200 Day

249

Lower Studies:

OPK $2.37* 0.04 ↓ 1.66%

*Delayed - data as of Jul. 3, 2019 - Find a broker to begin trading OPK now

Community Rating: Bullish

Edit Symbol List
Symbol Lookup

SYMBOL LIST VIEWS
FlashQuotes
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After Hours Quote
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Stock Report
Competitors
Stock Consultant
Stock Comparison
FUNDAMENTALS
Call Transcripts

OPK | SGMO | CLLS | S | CRSP | EDIT | NTLA | NDAQ

Save Stocks

Time Frame: 10 Years

Chart Display:

Chart Type:
OHLC | Bar | Line | Candlestick | Mountain

Indicators:
Splits | Earnings *

Moving Average:
None | 20 Day | 50 Day | 200 Day

Lower Studies:

$2.37 x 615,601,045 shares = $1,458,974,476

If U. of IL still owned 3%, worth $43,769,234

A Newer Way to Use SEC Filings

- Companies seem to be making much more detailed disclosures of deal terms in their 10-K's these days
  - 10-K's are much easier to find and search than attached agreements
- Example
  - Asian university developing a cellular therapy
  - Model: CAR-T's
    - A leading U.S. company
      - Juno Therapeutics
        - Five academic stage deal terms identified

A Newer Way to Use SEC Filings

- Fred Hutchinson Cancer Center
  - Upfront payment of $250,000;
  - An annual maintenance fee of $50,000 for the first four years thereafter minimum annual royalties of $100,000 per year;
  - With respect to JCAR014 and JCAR017, milestone payments of $6.75 million per licensed product
  - Low single-digit royalties
    - i.e., 3-4%
  - A portion of the payments from sublicensees, on a tiered basis, up to a cap.

A Newer Way to Use SEC Filings

- Memorial Sloan-Kettering Cancer Center
  - Upfront payment of $6.9 million;
  - Annual minimum royalties of $100,000 commencing of the fifth anniversary of the agreement;
  - Mid-to-high single-digit royalties on annual net sales of licensed products or the performance of licensed services by us and our affiliates and sublicensees
    - i.e., 5-9%;
  - $6.75 million in clinical and regulatory milestone payments for each licensed product including JCAR015

A Newer Way to Use SEC Filings

- Seattle Children's Research Institute
  - Upfront payment of $200,000;
  - Annual license maintenance fees of $50,000 per year for the first five years and $200,000 per year thereafter;
  - Low single-digit royalties based on annual net sales of licensed products and licensed services by us and our affiliates and sublicensees
    - i.e., 2-4%
  - For ***JCAR014 and JCAR017***, milestone payments totaling up to $13.3 million and up to $3.0 million in commercial milestone payments;
  - A percentage of sublicensee payments up to an aggregate of $15.0 million
- **Additive to Fred Hutchinson**

A Newer Way to Use SEC Filings

- St. Jude's Children's Research Hospital
  - An upfront payment of $25.0 million;
  - Low single-digit royalties
    - i.e., 2-4%
  - $100,000 minimum annual royalty for the first two years of the agreement, and a $500,000 minimum royalty thereafter
  - Milestone payments of up to an aggregate of $62.5 million for ***JCAR014 and JCAR017***
  - A percentage of sublicense income and settlement payments.
- **Also additive to Fred Hutchinson**

Juno vs Kite

- Juno and Memorial Sloan-Kettering sued Kite over Yescarta® in October 2017
  - 7,446,190
    - Expires May 2023
  - Kite bought by Gilead for $11.9 billion in August 2017
  - Juno bought by Celgene for $9 billion in January 2018
    - Celgene bought by BMS for $74 billion in January 2019
- Yescarta ® approved October 2017
  - Relapsed / refractory large B-cell lymphoma
    - 2019 sales $489 million
    - 2022 forecast $1.47 billion
- BMS awarded $752 million in damages in December 2019

Yescarta®

		2017	2018	2019	2020	2021	2022	2023
Sales		$20	$264	$489	$750	$1,100	$1,470	$819

Yescarta®

		2017	2018	2019	2020	2021	2022	2023
Sales		$20	$264	$489	$750	$1,100	$1,470	$819
Royalties	7.0%	$ 1	$ 18	$34	$53	$77	$103	$57

Yescarta®

		2017	2018	2019	2020	2021	2022	2023
Sales		$20	$264	$489	$750	$1,100	$1,470	$819
Royalties	7.0%	$ 1	$ 18	$34	$53	$77	$103	$57
Discount rate	11%	1.23	1.11	1	0.90	0.81	0.73	0.66

Yescarta®

		2017	2018	2019	2020	2021	2022	2023
Sales		$20	$264	$489	$750	$1,100	$1,470	$819
Royalties	7.0%	$ 1	$ 18	$34	$53	$77	$103	$57
Discount rate	11%	1.23	1.11	1	0.90	0.81	0.73	0.66
Discounted royalties		$1.72	$20.51	$34.23	$47.30	$62.49	$75.24	$37.74
Total								$279.24

Yescarta®

		2017	2018	2019	2020	2021	2022	2023
Sales		$20	$264	$489	$750	$1,100	$1,470	$819
Royalties	18.9%	$4	$50	$92	$141	$207	$277	$154
Discount rate	11%	1.23	1.11	1	0.90	0.81	0.73	0.66
Discounted royalties		$4.65	$55.24	$92.18	$27.37	$168.30	$202.62	$101.64
Total								$752.00

Reconciliation

- Juno-MSK License 5-9%
- Litigation 18.9%

- Reasons:
  1. In litigation, patent is presumed valid and infringed
     - In licensing, uncertainty as to validity
  2. In litigation, royalty is determined on the eve of infringement
     - Later of patent issuance and product launch
       - License is done at much earlier stage
       - Royalty rates for marketed products much higher than for preclinical / Phase 1 products

Look forward –

Discounted Cash Flow/Net Present Value

Time Value of Money

- DCF and NPV is all about the time value of money
  - Getting $1,000 next year isn't worth as much as getting $1,000 tomorrow
  - Spending $1,000 tomorrow is worse than spending $1,000 next year
- It's just like interest, but going backwards
  - Interest rate ➔ Discount rate

Net Present Value Calculations

- Take into account the facts that:
  - Expenses are certain and early
  - Return is later and uncertain
    - Product may not succeed
    - Market may not be there

Risk-Free

- Inflation currently is around 3%
- Assume we're happy with a 7% return
  - 3% for inflation
  - 4% as a return on investment
  - No risk
- If we invested $1,000 today, we would expect $1,070 in a year
- What about the second year? Another $70?
- More:
  - For the second year, we have $1,070 invested, not $1,000
  - Expect a return of $1,070 x 0.07, i.e., $75 for the second year

Going the other way

- We want back $1,070 in a year if we invest $1,000 today
- So, we would be willing to invest $1,000 / $1,070 or $934.57 today to get $1,000 back in a year
  - 7% of $934.57 is $65.42
  - $934.57 + $65.42 = $999.99
- So the value today of $1,000 in a year's time is $934.57
  - i.e., $934.57 is the Net Present Value of $1,000 one year out with a 7% discount rate
  - 7% is the interest rate going forward, or the discount rate going backwards

Discount Rate Formula

So, the Future Value (FV) 2 years in the future is:

$$\underline{\$1{,}000} + \underline{\$1{,}000 \times 0.07} + \underline{(\$1{,}000 + \$1{,}000 \times 0.07) \times 0.07}$$

Pres. Value | Interest year 1 | Interest year 2

$$FV = PV + PV * k + (PV + PV \times k) \times k$$

or $FV = PV * (1 + k)^2$

So the Net Present Value (PV) of an amount FV two years in the future is

$PV = FV / (1 + k)^2$

We would pay today $873.44 to get back $1,000 in two years

$873.44 is the Net Present Value of $1,000 in two years with a 7% discount rate

Turns out the formula generalizes to $PV=FV / (1 + k)^n$

where n is the number of years in the future

Multiple Payments

- If we wanted to get back $1,000 in each of the next two years, we would be willing to pay

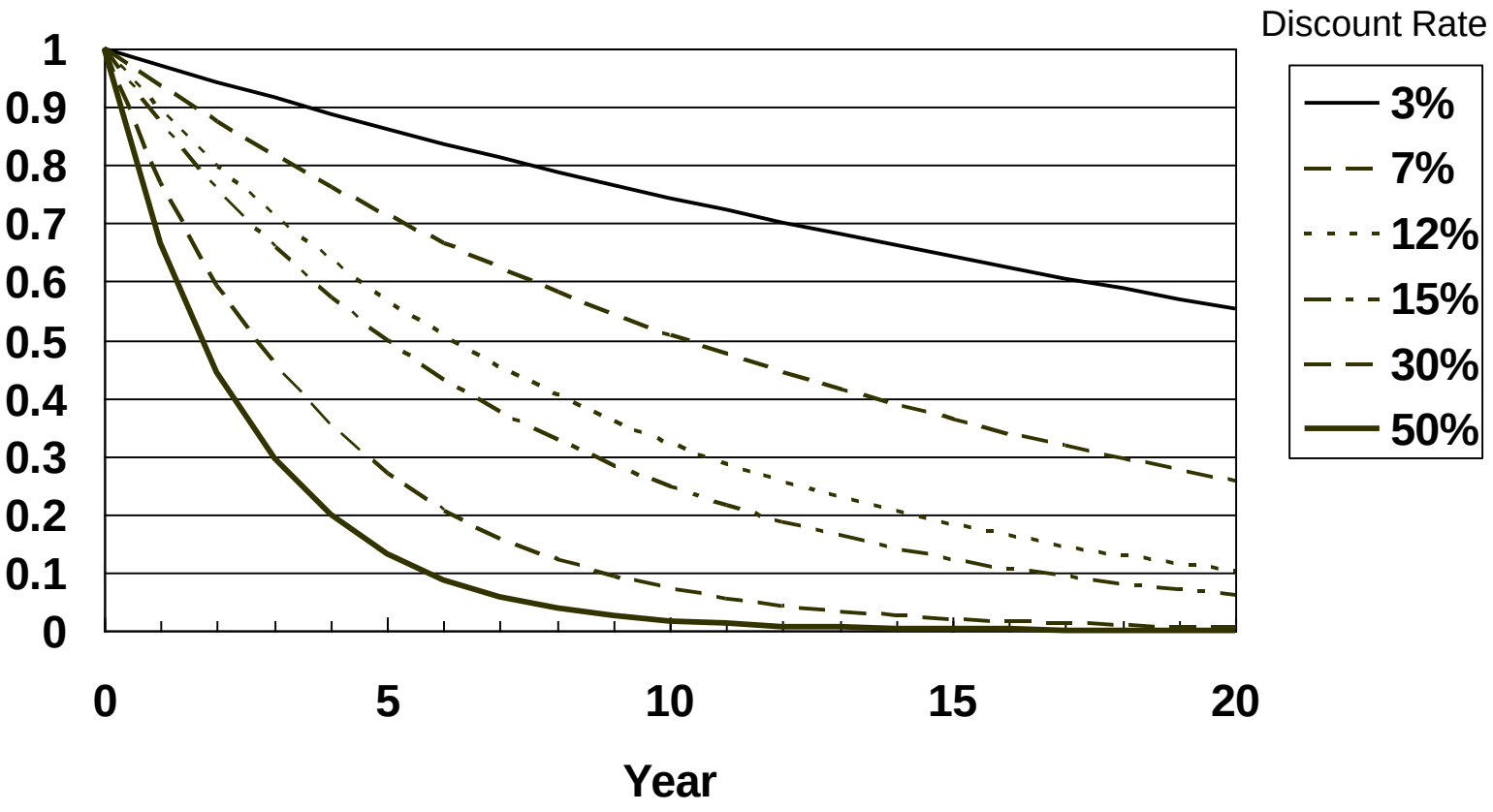
$$\$934.57 + \$873.44 = \$1,808.01$$

  - i.e., $1,808.01 is the Net Present Value of two $1,000 payments one and two years out with a 7% discount rate

Discount Rates

Inflation Rate	3%
Long Term T Bill Rate	7%
Corporate Bond Rate	12% (Blue Chip) - 18% (Junk)
Average Corporate Cost of Capital	15%
Corporate Investment Hurdle Rate	30%
VC Investment Hurdle Rate	50%

Effect of Discount Rate Over Long Periods



Net Present Value of $1,000 in Five Years

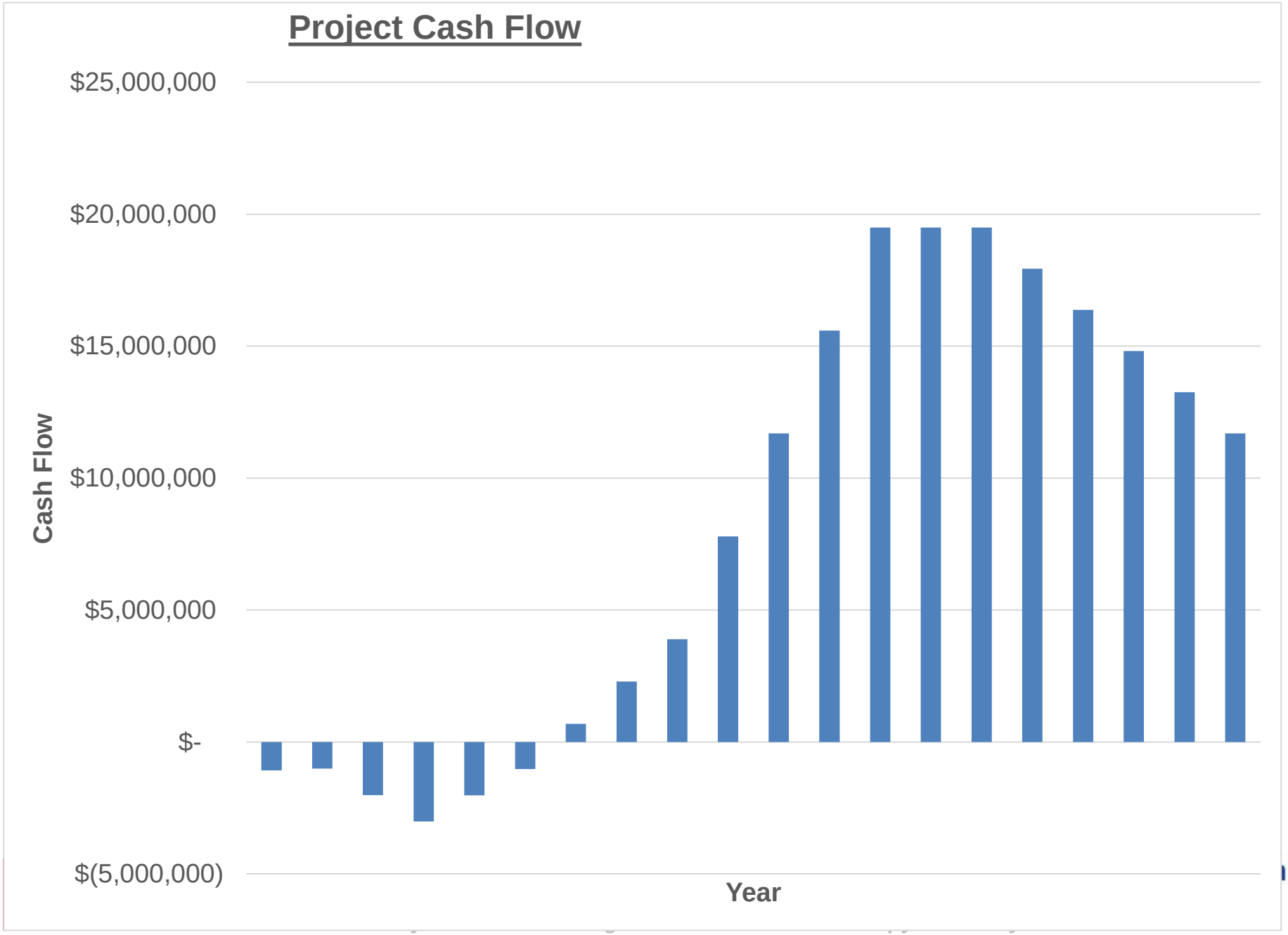
Formula is $\$1,000/(1+k)^5$

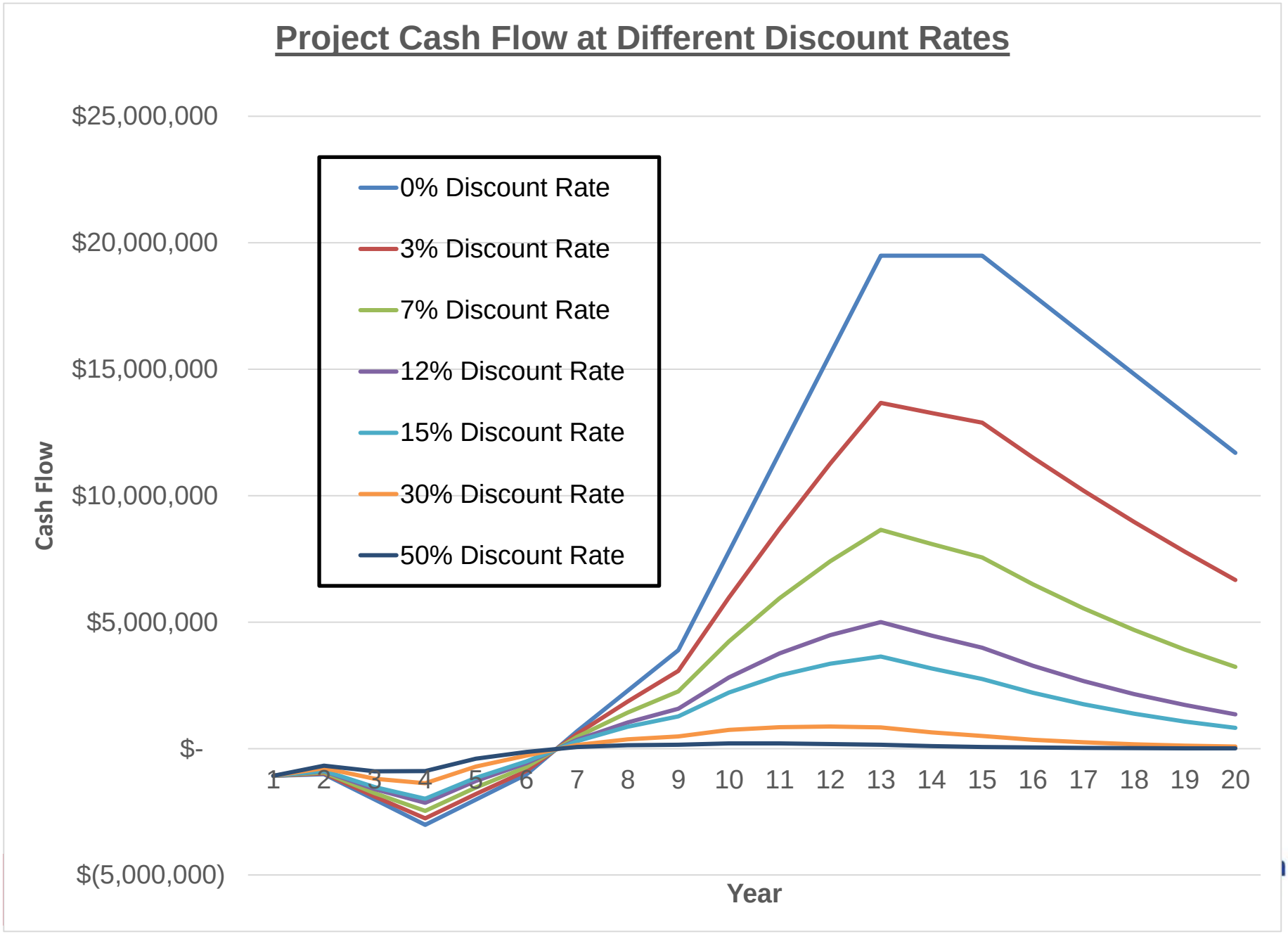
k	Value	Payback
3%	$862.61	1.15x
7%	$712.99	1.40x
12%	$567.43	1.76x
15%	$497.18	2.01x
30%	$269.33	3.71x
50%	$131.69	7.59x

Let's Look at the Licensed Project we Looked at Earlier

- $10 million invested over 6 years
- Sales start in year 7
- Operating costs
  - CoGS 5%
  - S&M 10%
  - G&A 5%
  - Ongoing R&D 2%
- Peak profits of $18 million in years 12-14
  - Declining to $11 million in year 20
- Total Net Income of $174 million
  - Net Profits exceed investment by $164 million

Looks like a great deal!


Project Cash Flow
$25,000,000
$20,000,000
$15,000,000
$10,000,000
$5,000,000
$-
$(5,000,000)
Cash Flow
Year


Project Cash Flow at Different Discount Rates
$25,000,000
$20,000,000
$15,000,000
$10,000,000
$5,000,000
$-
$(5,000,000)
Cash Flow
0% Discount Rate
3% Discount Rate
7% Discount Rate
12% Discount Rate
15% Discount Rate
30% Discount Rate
50% Discount Rate
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20
Year

So Is It Still A Good Deal?

- The answer depends on the discount rate

k	NPV	Payback
0%	$164.3	16.4x
3%	$107.0	10.7x
7%	$61.4	6.1x
12%	$31.1	3.1x
15%	$20.6	2.1x
30%	$1.0	0.1x
50%	$(2.7)	NM

Let's look at the 30% Case

- Licensee achieved their 30% return
- Project is still worth $979,937 today
- This amount is available to pay the licensor
- Could ask for $979,937 upfront
  - Unlikely -- puts all risk on licensee
- License terms in our example rate have an NPV of $864,014 with a 30% discount
  - Licensor NPV is still $115,922
- Goal seek: set Licensor NPV = $0 by varying running royalty rate
  - 5% ➔ 6.4%
- Or by increasing final milestone payment
  - $500,000 ➔ $930,412

Mechanics

- Easy to do in spreadsheets
- Excel has an NPV function
  - Handles up to 29 years
- Do your own
  - Calculate a Discount Factor for each year
  - First year is 1
  - Second year is 1/(1+k)
  - Third year is second year/(1+k)
  - Etc
  - Multiply each year's cash flow by that year's Discount Factor
  - Sum

Where Do You Get The Data?

- Ask the licensee for their projections from their business plan
- Read their annual reports if public
- Analysts reports
- Trust, but Verify!

Combining the 25 Percent Rule and NPV Analyses

- The Twenty Five Percent rule allocates Net Profits between licensor and licensee
  - Reflects past and future financial risk
- NPV is the best measure of Net Profits
  - It's the present value of Net Profits over the life of the project
- Apply NPV analysis of licensor's and licensee's cash flows and see how they compare
  - NPV Split analysis

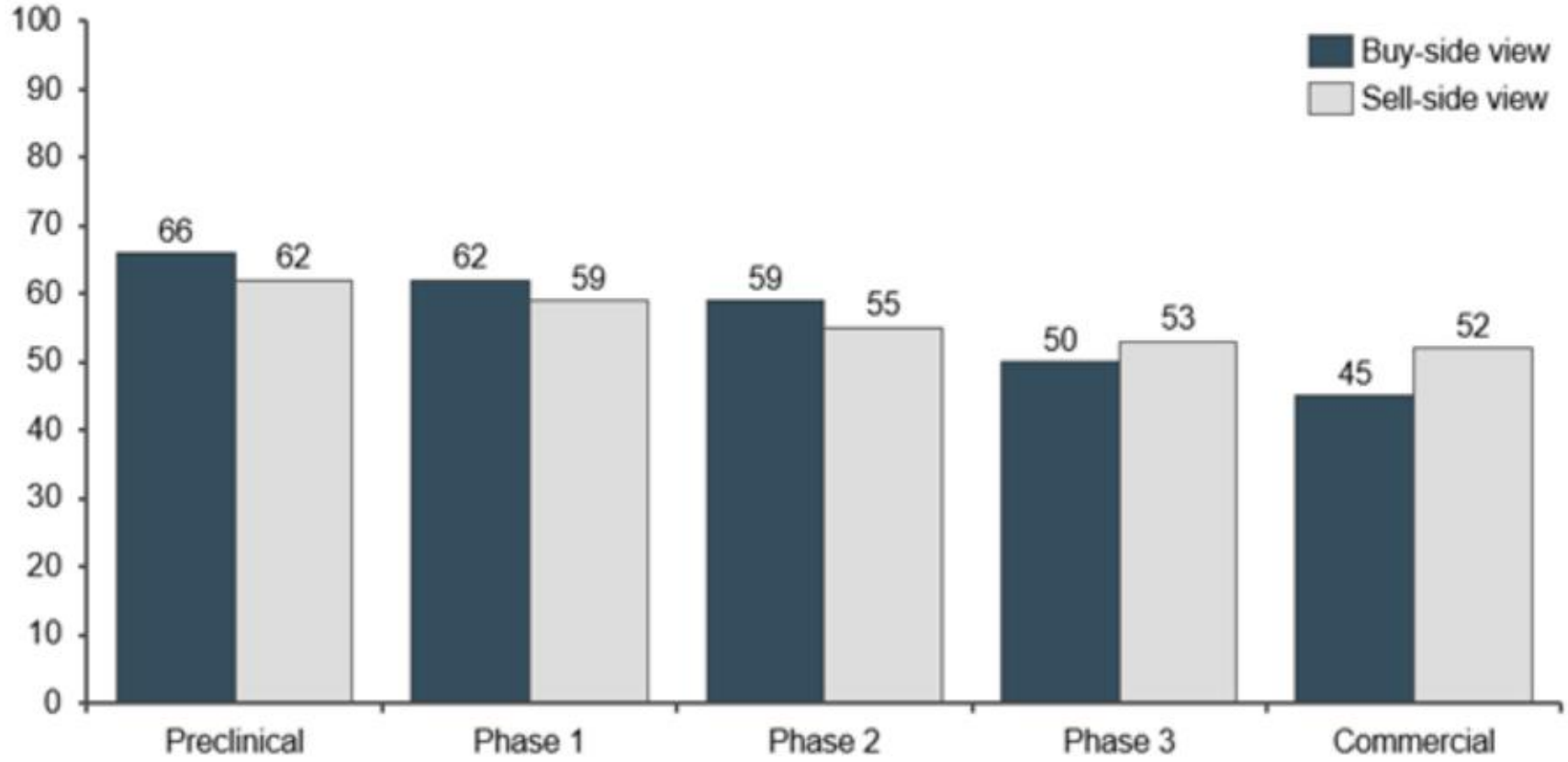
NPV Split Valuation

- Model the drug's commercialization
  - Calculate NPV
  - Create deal terms that split the NPV between licensor and licensee in percentages that depend on the stage of development of the drug
  - No "official" scale
    - Each company / B-D executive has their objectives
      - An early stage biotech entrepreneur
        - Pre-clinical 5-10%
        - Phase I 10%
        - Phase II 20%
      - A large pharma
        - Phase III 40%

NPV Split Valuation

Average percent of total asset value going to buyers, by development stage

Phase of development



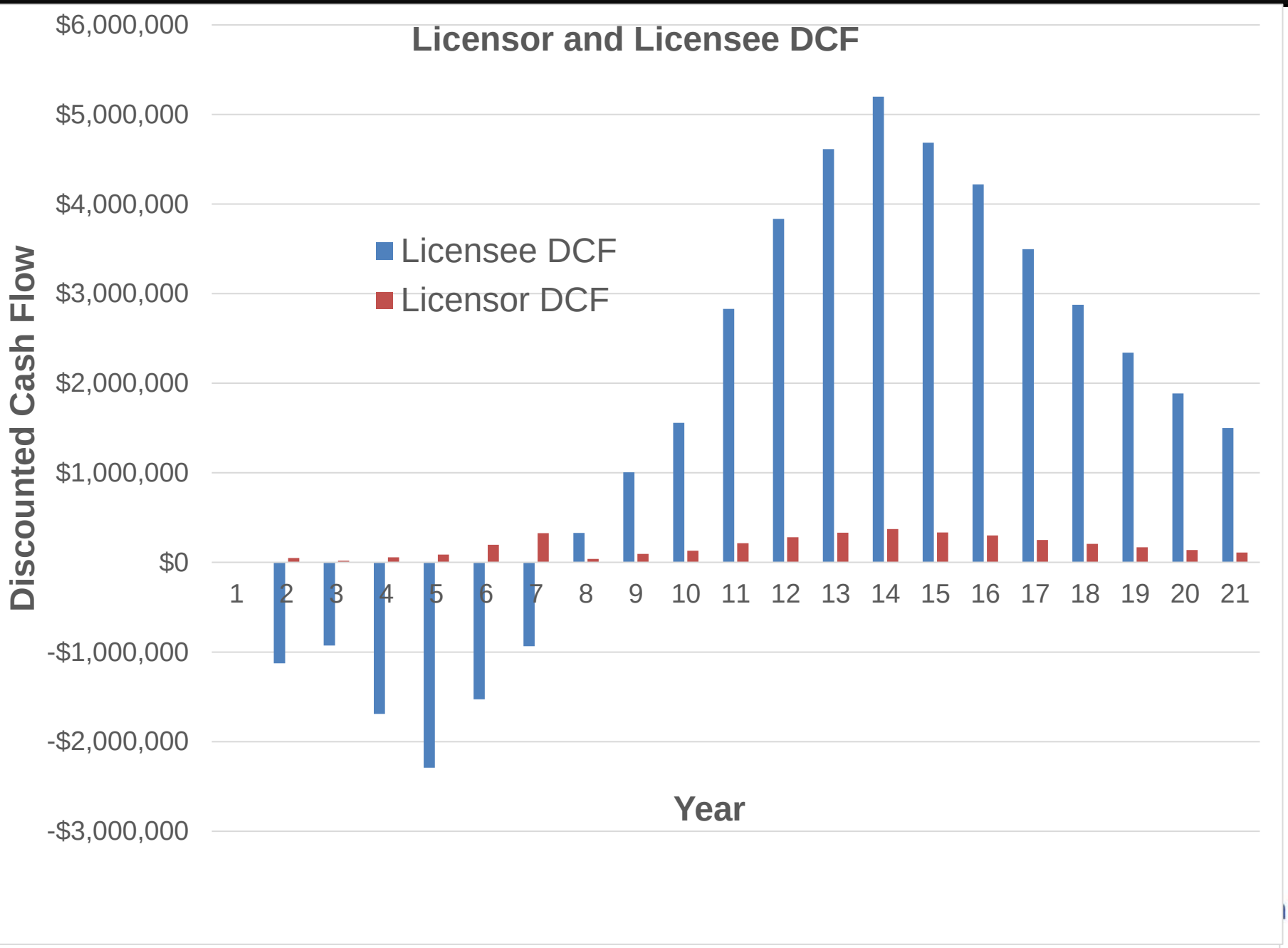
Source: L.E.K. HIC BD simulator survey (2020)

Example

- In the example we looked at above:
  - 11% discount rate:
    - Project NPV = $35.6 million
    - Licensee NPV = $31.9 million
    - Licensor NPV = $3.8 million
- NPV Split:
    - Licensor 10.4%
    - Licensee 89.6%

Product Cash Flow											
Year		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Product Sales		$ -	$ -	$ -	$ -	$ -	$ -	$ 1,000,000	$ 3,000,000	$ 5,000,000	$ 10,000,000
COGS		$ -	$ -	$ -	$ -	$ -	$ -	$ (50,000)	$ (150,000)	$ (250,000)	$ (500,000)
Patent Costs		$ (75,000)	$ (10,000)	$ (12,000)	$ (14,000)	$ (20,000)	$ (25,000)	$ (10,000)	$ (10,000)	$ (10,000)	$ (10,000)
S&M		$ -	$ -	$ -	$ -	$ -	$ -	$ (100,000)	$ (300,000)	$ (500,000)	$ (1,000,000)
G&A		$ -	$ -	$ -	$ -	$ -	$ -	$ (50,000)	$ (150,000)	$ (250,000)	$ (500,000)
R&D		$ (1,000,000)	$(1,000,000)	$(2,000,000)	$(3,000,000)	$(2,000,000)	$(1,000,000)	$ (100,000)	$ (100,000)	$ (100,000)	$ (200,000)
Product Cash Flow	$ 164,304,000	$ (1,075,000)	$(1,010,000)	$(2,012,000)	$(3,014,000)	$(2,020,000)	$(1,025,000)	$ 690,000	$ 2,290,000	$ 3,890,000	$ 7,790,000
Discount Factors	11.0%	1.00	0.90	0.81	0.73	0.66	0.59	0.53	0.48	0.43	0.39
Product DCF		$ (1,075,000)	$ (909,910)	$(1,632,984)	$(2,203,811)	$(1,330,637)	$ (608,288)	$ 368,902	$ 1,102,998	$ 1,687,974	$ 3,045,304
NPV		$ 35,595,998									

11	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
$ 15,000,000	$ 20,000,000	$ 25,000,000	$ 25,000,000	$ 25,000,000	$ 23,000,000	$ 21,000,000	$ 19,000,000	$ 17,000,000	$ 15,000,000
$ (750,000)	$ (1,000,000)	$ (1,250,000)	$ (1,250,000)	$ (1,250,000)	$ (1,150,000)	$ (1,050,000)	$ (950,000)	$ (850,000)	$ (750,000)
$ (10,000)	$ (10,000)	$ (10,000)	$ (10,000)	$ (10,000)	$ (10,000)	$ (10,000)	$ (10,000)	$ (10,000)	$ (10,000)
$ (1,500,000)	$ (2,000,000)	$ (2,500,000)	$ (2,500,000)	$ (2,500,000)	$ (2,300,000)	$ (2,100,000)	$ (1,900,000)	$ (1,700,000)	$ (1,500,000)
$ (750,000)	$ (1,000,000)	$ (1,250,000)	$ (1,250,000)	$ (1,250,000)	$ (1,150,000)	$ (1,050,000)	$ (950,000)	$ (850,000)	$ (750,000)
$ (300,000)	$ (400,000)	$ (500,000)	$ (500,000)	$ (500,000)	$ (460,000)	$ (420,000)	$ (380,000)	$ (340,000)	$ (300,000)
$ 11,690,000	$ 15,590,000	$ 19,490,000	$ 19,490,000	$ 19,490,000	$ 17,930,000	$ 16,370,000	$ 14,810,000	$ 13,250,000	$ 11,690,000
0.35	0.32	0.29	0.26	0.23	0.21	0.19	0.17	0.15	0.14
$ 4,117,037	$ 4,946,447	$ 5,571,038	$ 5,018,953	$ 4,521,579	$ 3,747,448	$ 3,082,343	$ 2,512,259	$ 2,024,894	$ 1,609,452


Licensor and Licensee DCF
$6,000,000
$5,000,000
$4,000,000
$3,000,000
$2,000,000
$1,000,000
$0
-$1,000,000
-$2,000,000
-$3,000,000
Discounted Cash Flow
Licensee DCF
Licensor DCF
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
Year

Example

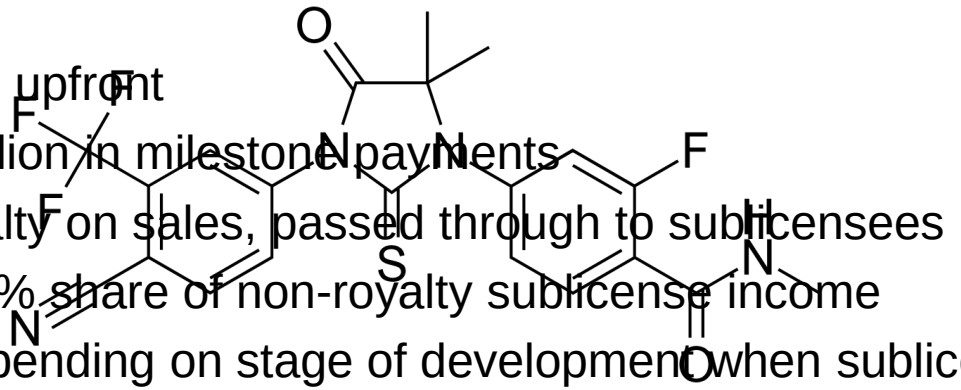
- What if licensee insists it won't go higher than a 7.5% NPV split?
- Use Goal Seek:
  - Set Licensor NPV split = 7.5%
  - Vary running royalty rate
    - ➔ 3.1%

Late Stage Drug Deals

- Phase III drug deals frequently are 50:50
  - Co-development
  - Co-promotion
  - 50:50 profit split
- Example: Medivation-Astellas – Xtandi

UCLA / Medivation / Astellas / Pfizer

- Medivation licensed ~170 diarylthiohydantoin compounds from UCLA in 2005
  - The RD Series
    - Bind and inhibit the androgen receptor
  - Preclinical
    - $15,000 upfront
    - $2.8 million in milestone payments
    - 4% royalty on sales, passed through to sublicensees
    - 25%-10% share of non-royalty sublicense income
      - Depending on stage of development when sublicense done



- RD162' became Xtandi®
  - Best drug for advanced prostate cancer
  - 2019 sales ~$4 billion

UCLA / Medivation / Astellas / Pfizer

- In 2009, Medivation did a deal with Astellas
  - Drug just entering Phase 3
    - Probably delayed deal till first patient dosed!
    - $110 million upfront
    - $335 million in development milestone payments
    - $320 million in sales milestone payments
    - 50 : 50 co-development and profit sharing in U.S.
    - Running royalties in RoW tiered low teens to low twenties;
      - Assume same as 2008 Medivation-Pfizer Alzheimer's/Parkinson's deal done in 2008:
        - 12% up to $500 million
        - 16% up to $1 billion
        - 20% up to $1.5 billion
        - 24% over $1.5 billion

UCLA / Medivation / Astellas / Pfizer

- In March 2016, UCLA monetized its royalty rights for $1.14 billion
  - Having already received ~$300 million in running royalties and sublicense income sharing payments
    - Model says $1.105 billion
- In August 2016, Pfizer acquired Medivation for $14 billion
    - Model says $16 billion

Look at the Build Up in Value

- 2005 $3 million
- 2009 $775 million
- 2016 $15.4 billion

NPV Analysis

- Sales Forecast
  - Actual sales through 2016
    - Medivation's 10-K's
  - Analysts reports 2016-2021
    - ➔ CAGR 14.3%
  - Grow at 14.3% through August 2027
    - Orange Book patent expiration
  - Assume 50:50 split US:RoW after 2019
- Profitability
  - Assume US profitability of 65% continues and applies in RoW

UCLA / Medivation / Astellas / Pfizer

- NPV's 2009:
  - UCLA: $716 million 2.9%
  - Medivation: $9,899 million 40.1%
  - Astellas: $14,086 million 57.0%
- Why does Astellas get 57% when co-development / co-promotion / 50:50 profit split
  - Medivation bore all costs up to Phase III
  - Medivation only gets tiered royalties in RoW

Risk Adjusted NPV (raNPV)

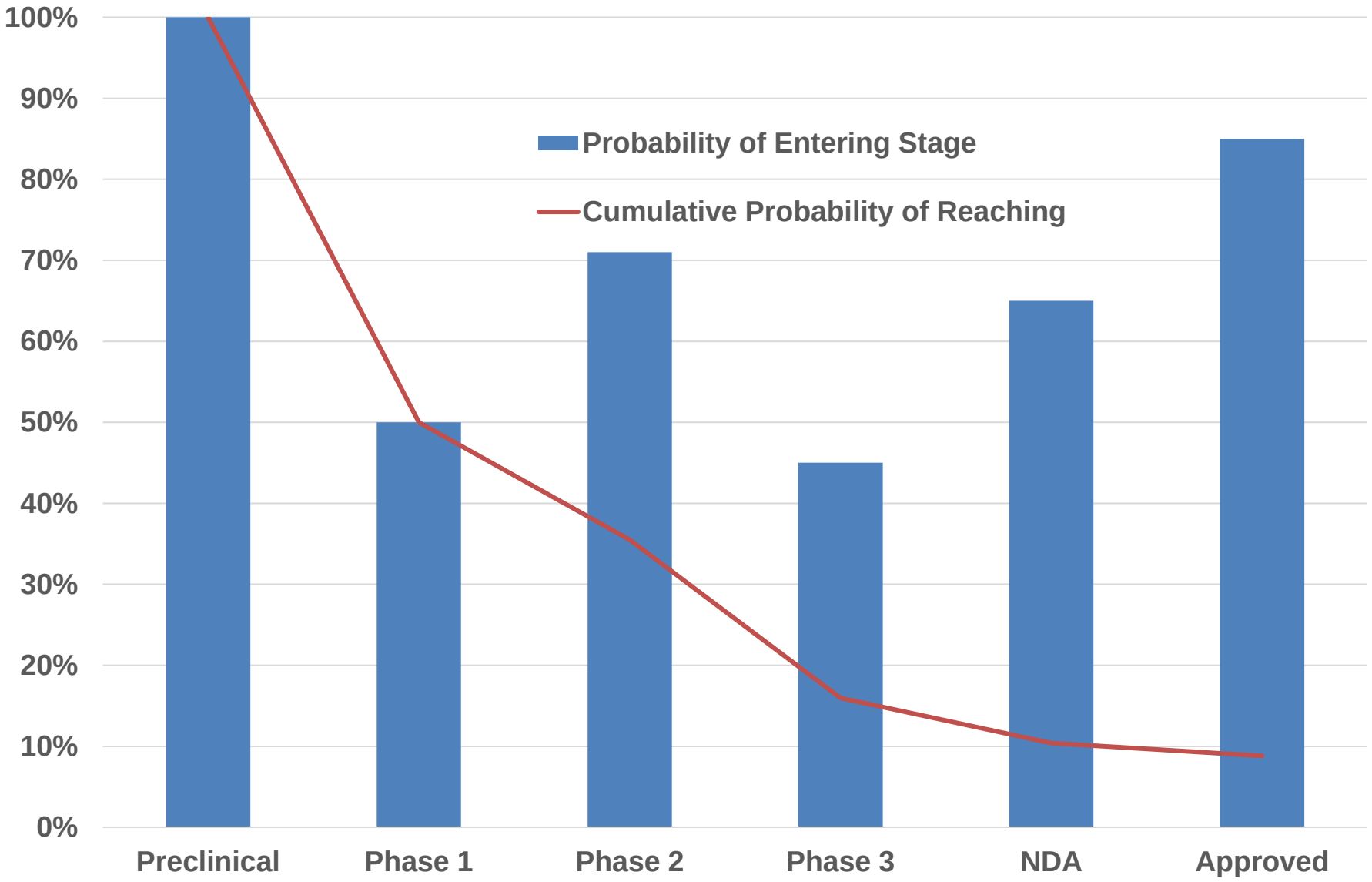
- Aka expected NPV or eNPV
- In 1980's, risk was accounted for by unbelievably high discount rates
  - Resulted in negative NPV's for drug development projects
  - So economically rational business people wouldn't develop drugs
- But they were developing them
  - So the model must be wrong
- Data on success rates by clinical stage accounts for risk explicitly
  - First available from Tufts Center for the Study of Drug Development in 1995
  - Then use a cost of capital discount rate, frequently 10-11%
- I invented (and published!)[1] this in 1996
  - Pre State Street Bank
- Big pharma's develop both NPV's and raNPV for portfolio management

[1] "Risk Adjusted Net Present Value -- a New Approach to Valuing Early Stage Technologies", A. Stevens, *Journal of Biotechnology in Healthcare*, 2, 335-351, (Spring, 1996)

Stage Success Rates

	DiMasi					Median
NCE's	1995	2010	FDA	BIO	Takebe	
Preclinical			50.0%		25.7%	37.9%
Phase 1	75.0%	71.0%	40.0%	61.3%	80.0%	71.0%
Phase II	48.0%	45.0%	45.0%	26.5%	47.6%	45.0%
Phase III	75.0%	64.0%	65.0%	48.7%	66.7%	65.0%
NDA	85.0%	93.0%	85.0%	78.0%	77.8%	85.0%

Stage and Cumulative Success Rates



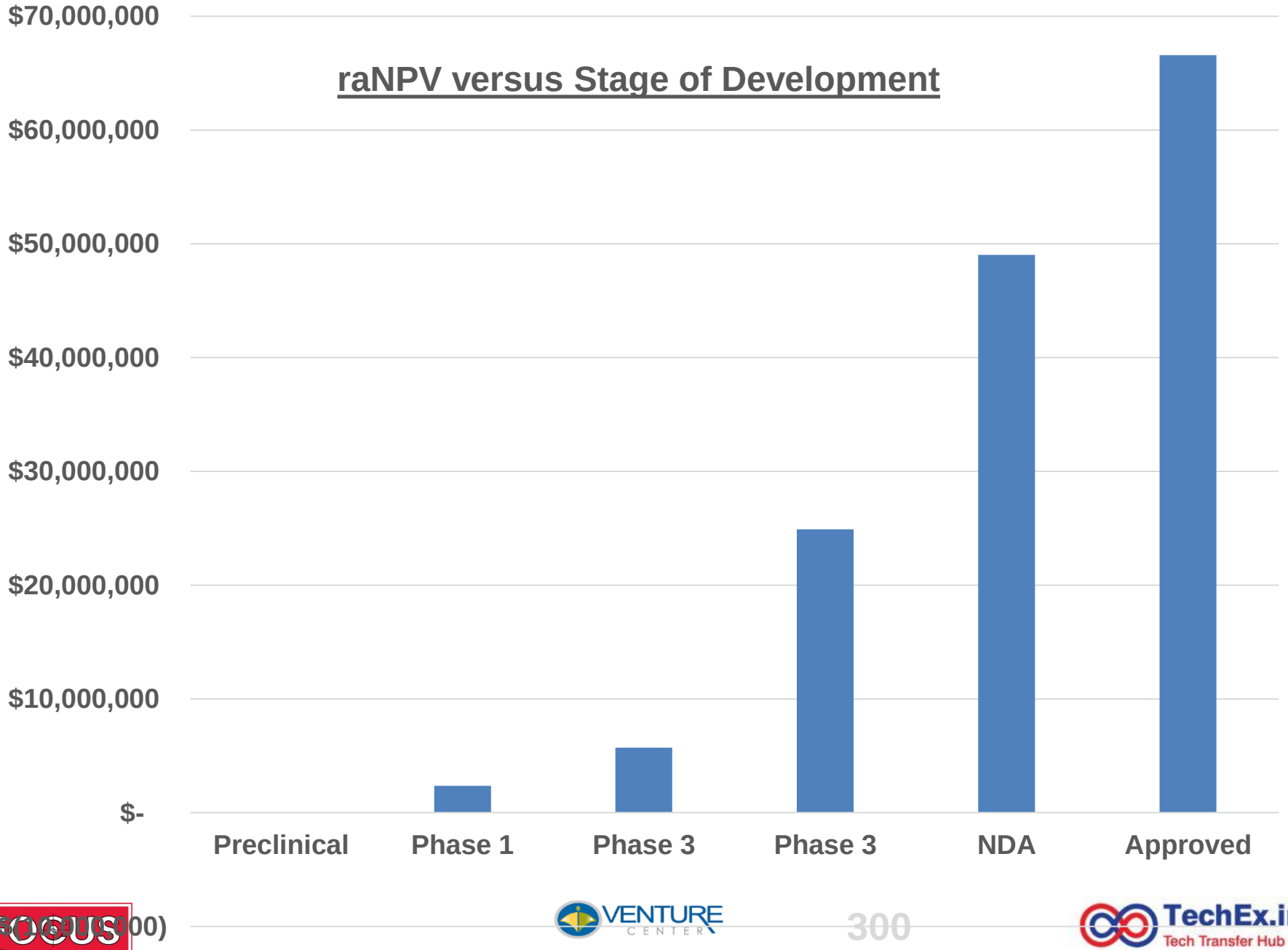
raNPV Analysis of Our Example

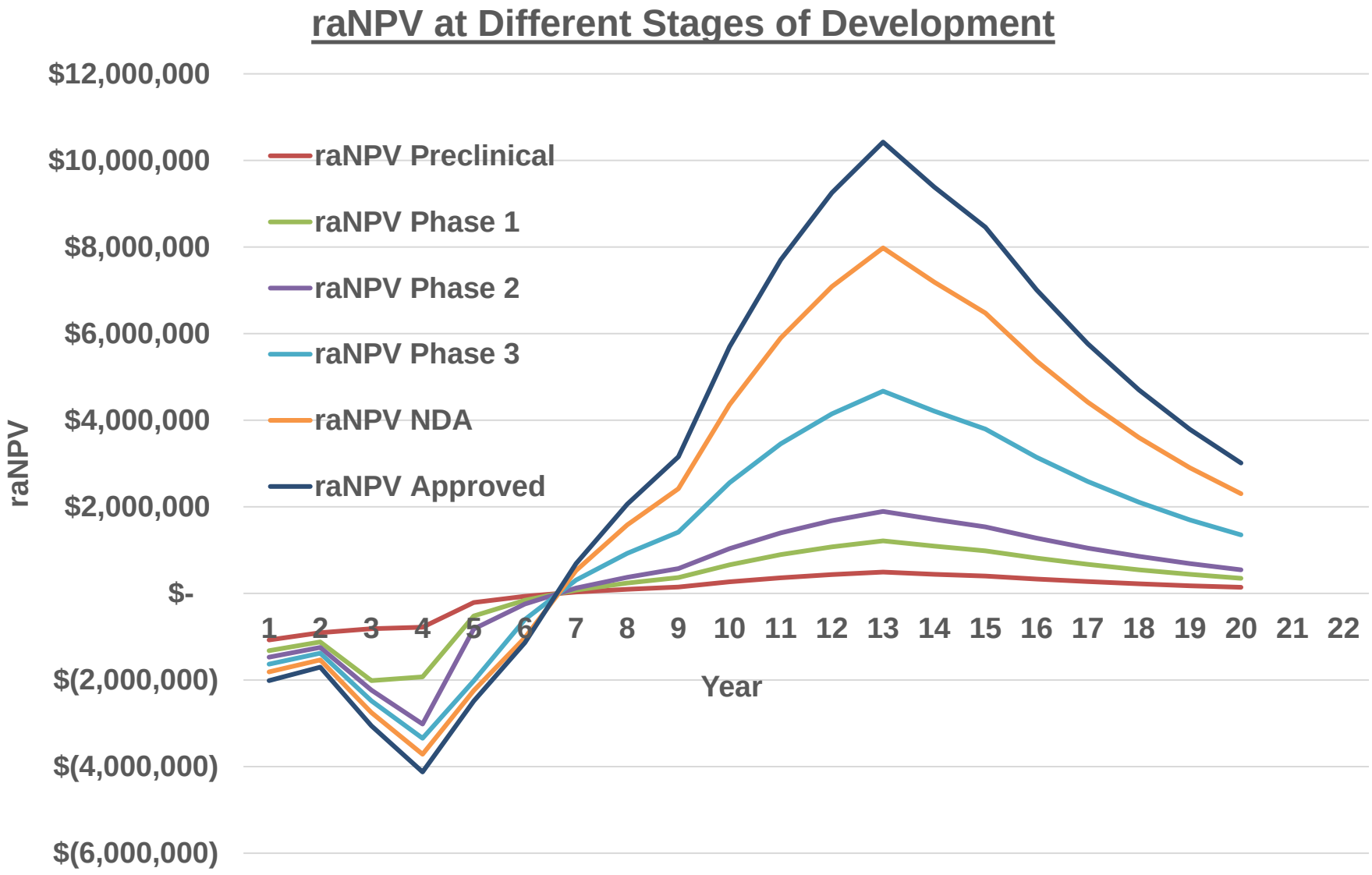
raNPV Analysis										
Year		1	2	3	4	5	6	7	8	9
Preclinical				Phase 1	Phase 2	Phase 3	NDA	Approved		
Cash Flow	$ 164,304,000	$ (1,075,000)	$(1,010,000)	$(2,012,000)	$(3,014,000)	$(2,020,000)	$(1,025,000)	$ 690,000	$ 2,290,000	$ 3,890,000
Prob of Success	1.00	1.00	0.50	0.71	0.45	0.65	0.85			
Cumulative PoS		1.00	1.00	0.50	0.36	0.16	0.10	0.09	0.09	0.09
ra Cash Flow	$ 10,808,068	$ (1,075,000)	$(1,010,000)	$(1,006,000)	$(1,069,970)	$ (322,695)	$ (106,433)	$ 60,901	$ 202,120	$ 343,339
Discount Factors	11%	1.00	0.90	0.81	0.73	0.66	0.59	0.53	0.48	0.43
raNPV Preclinical	$ (32,750)	$ (1,075,000)	$ (909,910)	$ (816,492)	$ (782,353)	$ (212,569)	$ (63,163)	$ 32,560	$ 97,353	$ 148,984

10	11	12	13	14	15	16	17	18	19	20
$ 7,790,000	$ 11,690,000	$ 15,590,000	$ 19,490,000	$ 19,490,000	$ 19,490,000	$ 17,930,000	$ 16,370,000	$ 14,810,000	$ 13,250,000	$ 11,690,000
0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09
$ 687,560	$ 1,031,781	$ 1,376,003	$ 1,720,224	$ 1,720,224	$ 1,720,224	$ 1,582,535	$ 1,444,847	$ 1,307,158	$ 1,169,470	$ 1,031,781
0.39	0.35	0.32	0.29	0.26	0.23	0.21	0.19	0.17	0.15	0.14
$ 268,784	$ 363,377	$ 436,583	$ 491,710	$ 442,982	$ 399,083	$ 330,757	$ 272,053	$ 221,737	$ 178,721	$ 142,053

raNPV at Different Stages of Development

Stage	raNPV
Preclinical	$ (32,750)
Phase 1	$ 2,364,905
Phase 3	$ 5,718,237
Phase 3	$ 24,906,689
NDA	$ 49,022,560
Approved	$ 66,579,272





List Pricing

- As you get more familiar with tech transfer and do more deals, you'll have a good feel for what a technology is worth
  - Won't need to go through a specific valuation exercise for each one

Getting Paid

- Important to have a good tracking system
  - Know when reports and payments are due
    - Follow-up the next day if not received
- Trust but verify
  - Track licensee's progress
    - Website
    - Press releases
    - SEC filings
    - Google Alert
- Tracking responsibility clearly defined in office
  - Licensing officer
  - Alliance manager
    - Large companies generally have a different person manage the alliance

Forecasting Income

- Leadership will want to know what income they can expect
  - One year forecast probably part of budget presentation
    - Should be able to forecast one year out with reasonable confidence
      - Ask licensees for sales forecasts for marketed products
      - Compare with public announcements
    - Wild card will be new product launches
      - Timing
      - Market success
  - The longer the forecast timeline the more uncertainty
    - Try to avoid firm forecasts
    - Talk about the pipeline
    - If you have to, probability-adjust numbers
  - Prepare for major patent expirations years in advance
    - Amazing how many Directors retire the year a major patent expires!

And if all else fails……

5%

THIS INDENTURE made this 30th day of May, A.D.

1922

BETWEEN

The Governors of the University of Toronto,

of the First Part;

-and-

The Eli Lilly Company, Incorporated under the laws of the State of Indiana, of Indianapolis, in Marion County and State of Indiana.

of the Second Part.

WHEREAS the Party of the First Part is the owner of a pancreatic extract or product for the treatment of diabetes mellitus and a process for preparing the same for which application for Letters Patent was filed in the United States Patent Office on or about the 22nd day of May, A. D. 1922 under Serial Number 562, 835.

AND WHEREAS the party of the First Part is not in a

Patent granted for the said process and product and any improvements thereto, on the same favourable terms as other firms similarly licensed by the said party of the first part and the said party of the second part in consideration of the said license shall pay to the party of the first part a royalty of 5% of the net selling prices which the said party of the second part receives for the product, during the life of such patent.

(10) In the event of the said party of the second part, during the said experimental period or subsequently during the period of the license referred to in paragraph 9, shall develop, improve, or simplify methods of producing the said pancreatic extract, full and complete information regarding such methods shall be communicated by the party of the second part to the said party of the first part for use in the preparation of the said extract.

For More Information

- Intellectual Property Valuation Manual For Academic Institutions
  - Ashley J. Stevens
    - World Intellectual Property Organization (WIPO), Geneva, Switzerland, March 2016,
    - Available at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=332588

Questions?

Tea / Coffee

Session 6:
Spin-Out Creations and the Art of the Cap Table

Acknowledgements

- Lita Nelsen, MIT
- Steve Sammut, Penn
- Teri Wiley, Mt. Sinai Hospital

“Equity is just cash that hasn’t turned green yet”

Joyce Brinton
Harvard University
1998

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

NUMBER 3

SHARES 33,333

GENMAP, INC.

3,900,000 SHARES COMMON STOCK – PAR VALUE $ 01

FULLY PAID NON-ASSESSABLE

This Certifies that Ashley J. Stevens is the registered holder of Thirty-Three Thousand Three Hundred Thirty-Three ------- Shares

GENMAP, INC.

transferable only on the books of the Corporation by the holder hereof in person or by Attorney upon surrender of this Certificate properly endorsed.

COMMON

In Witness Whereof, the said Corporation has caused this Certificate to be signed by its duly authorized officers and its Corporate Seal to be hereunto affixed this 15th day of March A.D. 19 89

President

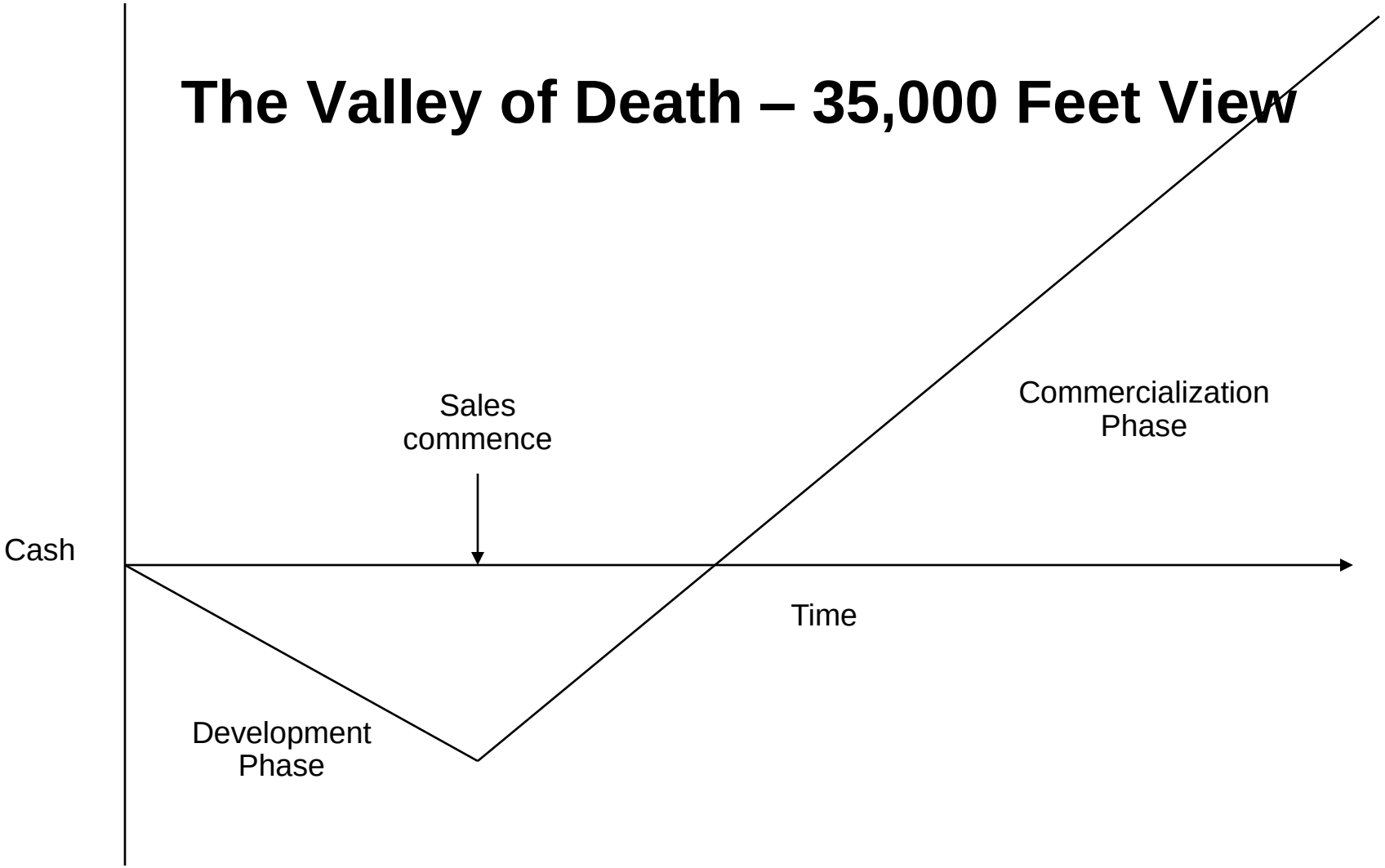
Ashley J. Stevens
Secretary

Agenda

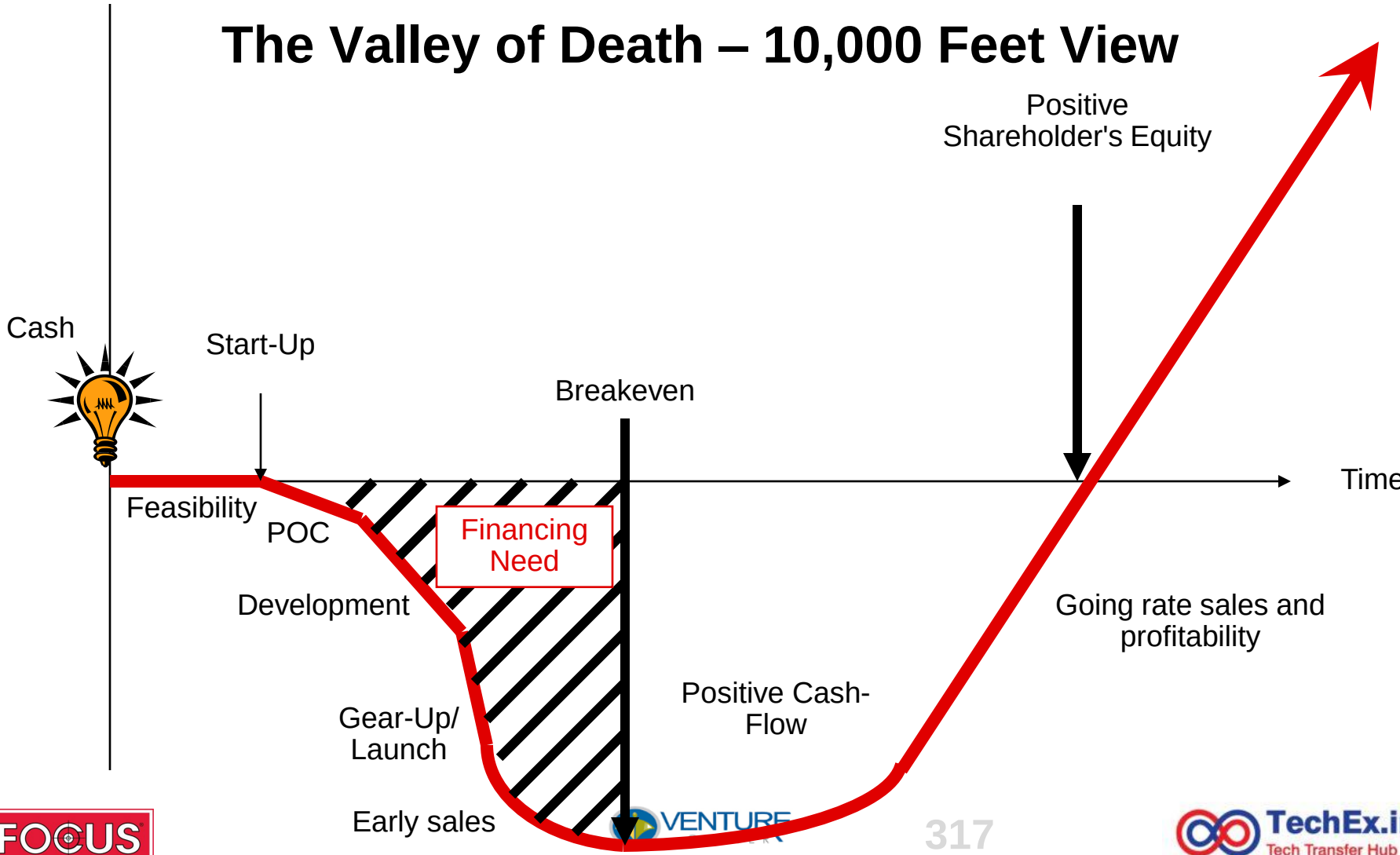
- The Financing Cycle of a Start-Up Company
- What is Equity?
- Ideal Cycle of Funding
- The Dark Side
- Exit Mechanisms
  - IPO
  - Acquisition

The Financial Life Cycle of a Company

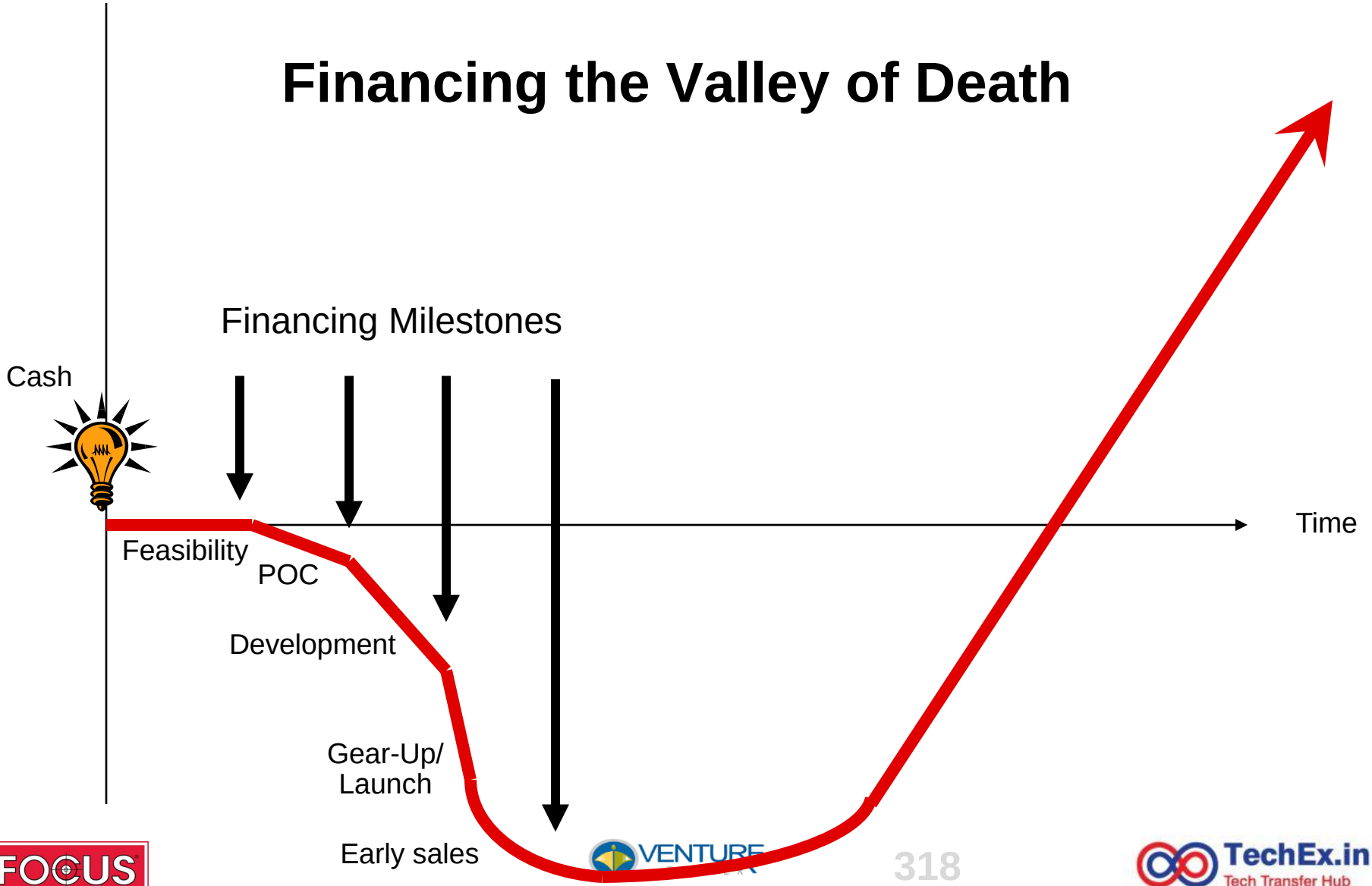
The Valley of Death – 35,000 Feet View

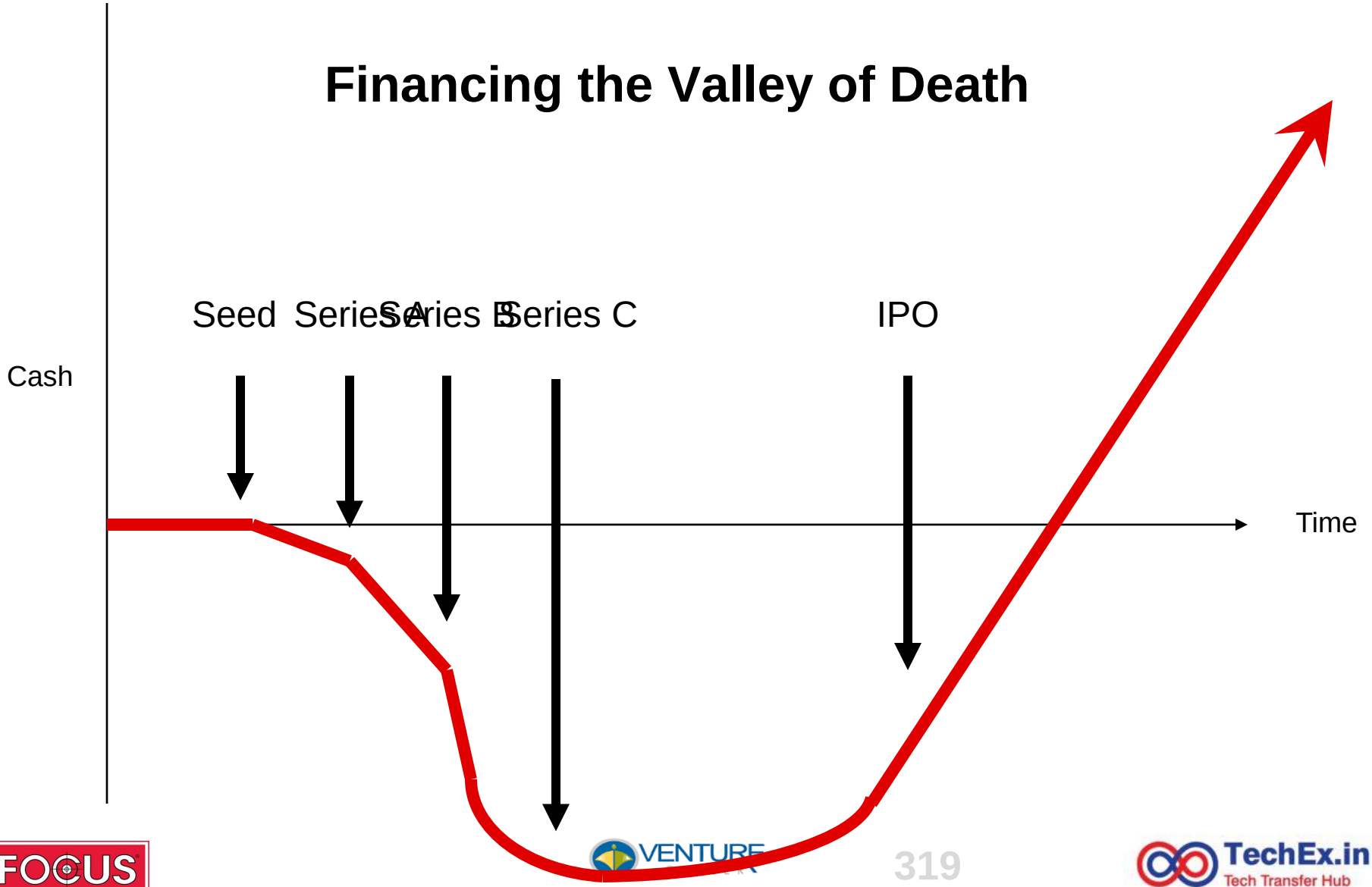


The Valley of Death – 10,000 Feet View



Financing the Valley of Death





How Does a University Get Equity in a Company?

- Part of a license
  - Either in lieu of upfront fee, plus normal other cash royalty terms
    - Milestones, annual minimums, running royalties, etc.
  - Or, fully paid up
- Best practice is the first
  - Equity gives some return if the license is terminated
  - Cash terms give a return if product succeeds but equity is diluted to nothing
- Example: BioVex
  - UCL spinout
  - All equity, UCL and prof each got 25% of initial equity
    - Got as far as a Series F, raised $150 million including one down round
    - Bought by Amgen for $425 million plus $575 million in milestones
      - Product was approved.
        - Professor and UCL made £475 (each)
      - Postdoc joined the company, kept getting options, made many £mm

How Does a University Get Equity in a Company?

- Providing services
  - Incubation space
  - Interim management
    - Writing the business plan
    - Fund raising
  - Recruiting the management team
- Investing in the company
  - Needs an investment fund

University Financing

- Most university assistance to spin-outs is in-kind
  - Business plan development
  - Management team recruitment
  - Incubation
  - Pre-seed grant funding
- Some universities have their own funds
  - Saved from a “big hit”
  - From operating budget
  - Part of endowment
  - Alumni
  - Philanthropic

Capitalization Tables

What is a Cap Table and Why Are they Important?

- The Cap Table shows:
  - What the company is worth;
  - Who owns how much of the company; and
  - How much their share is worth.
- The Cap Table's changes over time shows:
  - How the company's value is changing
    - Up or down
  - Who's going to get how much when the company is sold or goes public.

The Cap Table Pre-Financing

Dividing the Pie Between the Founders

- Easy route is equal shares
  - Simplistic
    - Different people bring different things and make different commitments
- A rational analytical approach:
  - Multivariable Contribution Analysis
    - Remember: Always have a basis for your proposals

Multivariable Contribution Analysis
1. Factors and Weights

	Weight	Founder 1	Founder 2	Founder 3	Founder 4
Idea	7				
Business Plan	2				
Technology -- patents	7				
Technology – know-how	4				
Commitment and Risk	5				
Domain Expertise	7				
Responsibilities	6				

Multivariable Contribution Analysis
2. Absolute Scores

	Weight	Founder 1	Founder 2	Founder 3	Founder 4
Idea	7	6	2	2	0
Business Plan	2	2	7	1	0
Technology -- patents	7	0	0	0	10
Technology – know-how	4	0	0	5	5
Commitment and Risk	5	4	2	4	2
Domain Expertise	7	0	7	0	0
Responsibilities	6	0	6	4	0

Multivariable Contribution Analysis
3. Weighted Scores and Percentages

	Founder 1	Founder 2	Founder 3	Founder 4	Total
Idea	42	12	4	0	58
Business Plan	4	14	7	0	25
Technology -- patents	0	0	0	70	70
Technology – know-how	0	0	10	10	20
Commitment and Risk	20	10	20	10	60
Domain Expertise	0	49	0	0	49
Responsibilities	0	36	24	0	60
	66	121	65	90	342
	19.3%	35.4%	19.0%	26.3%	

How Much for the University?

- US
  - Two Models
    - Anti-dilution model
      - "Give me 5% and keep me at 5% till $5 million in equity financing has been raised"
        - Often combined with pre-emptive rights
          - Right to invest to maintain that 5%
          - Needs an investment fund to be able to exercise
            - Osage Partners
    - Co-Founder Model
      - University treated just like other founders
        - E.g., 4 founders plus university – 20% each
      - Diluted equally in subsequent financings
  - We'll compare the two approaches quantitatively later.

Columbia University Model

- Standard equity model for every start-up
  - For all sectors
    - 5% ownership
    - Maintained till company closes a Series A financing typical for that sector
  - Royalty terms vary by sector
    - Higher for software and pharmaceuticals
    - Lower for engineering, manufacturing
      - Depends on profitability
- Start-up and Columbia bring data relevant to that sector as basis for negotiations

University Equity Models

- U.K. Model (Big 6 at least)
  - University 50%
  - All other founders 50%
- Frequently all equity – fully paid up
  - No royalties, milestones, etc.
- There has been pushback
  - Oxford sued by a spin-out
    - Oxford Nanoimaging
      - Founders round 50% university / 50% two scientific founders
      - Tiered royalties 3.5-6%
    - Judge ruled for Oxford
      - Oxford Nanoimaging trying to appeal
  - Oxford has reduced its starting position to 20%
    - Government looking into it

University Equity Models

- Has resulted in some interesting initiatives
  - Imperial Innovations plc
    - Publicly traded on AIM
  - IP Group (formerly IP2IPO)
    - Funded new Oxford Chemistry building
    - Deals with a number of U.K. universities
      - Southampton, Leeds, York, Kings, Bristol, Surrey, Bath, Glasgow
  - Oxford Science Enterprises
    - £850 million
  - Cambridge Innovation Capital
    - £500 million
  - UCL Technology Fund
    - Raised £54 million, trying for second fund of £250 million
  - Northern Gritstone -- Manchester / Leeds / Sheffield
    - Raising £500 million

The Cap Table During Financing

Definitions

Common Stock

- Stock represents a partial ownership in a company
  - “Shares” of:
    - Assets
    - Income
- Not debt
  - No obligation to repay
- Common stock generally paid for by effort
  - The original “sweat equity”
    - Founders, management, technology, consultants
  - Freely available pre-financing
  - Financial sources will tightly control creation after financing
- Generally, the stock that gets sold in a public offering or M&A
  - All other classes of stock get converted to common the night before

Definition

Founders' Stock

- The first stock sold in a company by the people who found the company
- Common stock
- Sold at par value – typically $0.01 or $0.001/share
  - Company has no assets at this time
    - Fair Market Value
  - Provides the initial "running around money"
    - e.g., 2 million shares @ 1¢/share = $20,000
      - Enough to pay incorporation costs
  - Maximizes tax benefits for Founders
    - No immediate tax liability
    - All gain is taxed at Capital Gains rates


INCORPORATED UNDER THE LAWS OF
THE STATE OF DELAWARE

NUMBER 3

SHARES 33,333

GENMAP, INC.

3,900,000 SHARES COMMON STOCK — PAR VALUE $ 01

FULLY PAID NON-ASSESSABLE

This Certifies that Ashley J. Stevens is the

registered holder of Thirty-Three Thousand Three Hundred Thirty-Three ------- Shares

GENMAP, INC.

transferable only on the books of the Corporation by the holder hereof in person or by Attorney upon surrender of this Certificate properly endorsed.

COMMON

In Witness Whereof, the said Corporation has caused this Certificate to be signed by its duly authorized officers and its Corporate Seal to be hereunto affixed this 15th day of March A.D. 19 89

President

Ashley J. Stevens
Secretary

Founders Round

Price per Share	$0.01			
	Shares	Raised	%	Value
Professor	500,000	$5,000	20%	$5,000
Postdoc A	250,000	$2,500	10%	$2,500
Postdoc B	250,000	$2,500	10%	$2,500
University	500,000	$5,000	20%	$5,000
CEO	1,000,000	$10,000	40%	$10,000
Total	2,500,000	$25,000	100%	$25,000

Issued and outstanding	2,500,000
Fully diluted	2,500,000
Raised in this round	$25,000
Cumulative raised	$25,000

The #1 Mistake of Start-Ups

- Giving out too much Founders' equity to people who don't join the company
  - Extraordinarily demotivating to people who do
  - VC's may insist it get undone
    - See *startup.com*

You Need Committed People

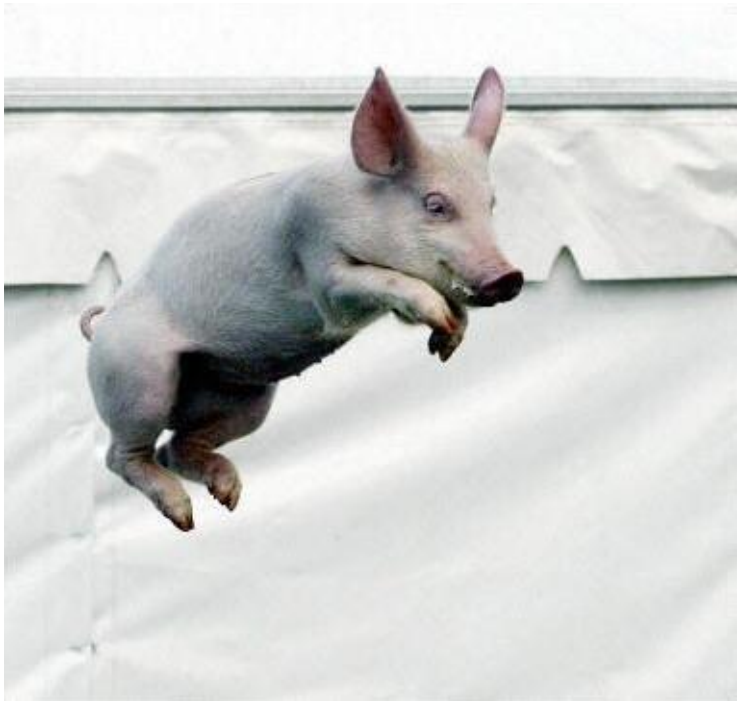
- What's the difference between involvement and commitment?

Think Back to the Last Time You Had Egg and Bacon for Breakfast

It Took Two Animals to Produce that Meal

A Chicken

&

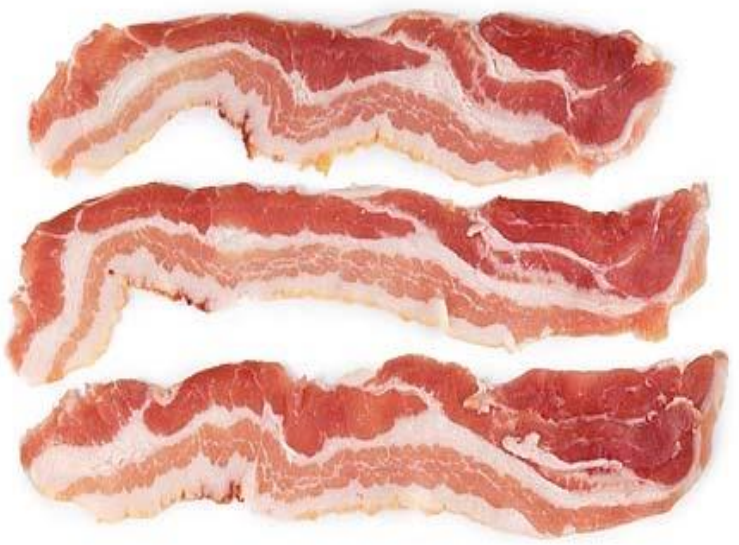


a Pig

Now the Chicken

was certainly involved

But the Pig



was definitely **COMMITTED!**

The Solution

- Have an earn-in
  - Make sure people commit
    - And stay committed!
  - 4 years is typical
    - 1 year cliff
- Inventors of the technology
  - Vest all their Founders' stock when they assign their interest in the IP to the company

Seed Round

- First “serious” money going in
  - $150,000 - $1,000,000
- Fund to proof of principle stage
  - If at proof of principle stage, may be able to go straight to VC rounds
- Sources
  - Friends and family (aka, Friends, family and fools)
  - Angels
  - Bands of Angels
  - Seed funds
    - Economic development funds
- VC’s won’t invest this little
  - High transaction and due diligence costs

Definitions

Issued and outstanding

Shares which have been paid for and for which a share certificate has been issued

- As opposed to shares which have been promised to someone through an option or warrant

Authorized Capital

Number of shares the Board of Directors has authorized the company to sell

- Gets increased from time to time

Definition

Pre-Money

- The Heart of Start-Up Valuation
  - The price of the company's stock agreed by the buyer (the new investor) and seller (the company)

A NEGOTIATED FIGURE

- Not an accounting-derived figure
- Determines how much of the company the next round of investment will buy and hence the dilution to existing shareholders

Example

- Suppose $2 million is to be raised at $1/share
  - If Pre-Money value of company is $1 million
    - 1,000,000 shares already exist
    - 2,000,000 shares will need to be sold
      - 2x what already exists
    - New shareholders will now own two thirds of the company
    - Dilution is by two thirds
  - If Pre-Money value of company is $5 million
    - 5,000,000 shares already exist
    - 2,000,000 shares will need to be sold
      - Only 40% more than currently exist
    - New shareholders will own 28.6% of the company
    - Dilution is by 28.6%

Some Fundamental Relationships

Number of Shares Sold	=	Amount Raised / Price Per Share
Post-Money Value	=	Pre-Money Value + Amount Raised
% Dilution	=	Amount raised / Post-Money Value

Seed Round

- Founders want to raise $200,000
  - Decide to price at 80¢/share
- How much of the company should they give up?
  - 10% ownership “feels” about right
  - Values the company at ~$2,000,000 pre-money
- Professor’s stake now worth $400,000

Seed Round

Price per Share	**$0.80**			
	Shares	**Raised**	**%**	**Value**
Professor	**500,000**		**18.2%**	**$400,000**
Postdoc A	**250,000**		**9.1%**	**$200,000**
Postdoc B	**250,000**		**9.1%**	**$200,000**
University	**500,000**		**18.2%**	**$400,000**
CEO	**1,000,000**		**36.4%**	**$800,000**
Seed investors	**250,000**	**$200,000**	**9.1%**	**$200,000**
Total	**2,750,000**	**$200,000**	**100.0%**	**$2,200,000**

Issued & outstanding	**2,750,000**
Fully diluted	**2,750,000**
Raised in this round	**$200,000**
Cumulative raised	**$225,000**
Pre-Money	**$2,000,000**
Post-Money	**$2,200,000**

Definitions

Convertible Debt (Note)

- A debt obligation of a company that is convertible into stock
  - i.e., A loan that won't be repaid
- Used when the parties don't want to set the price of the stock at the time the investment is made
- Simple document
  - Legal costs low

Dilution

- A decrease in a shareholder's percentage ownership without a reduction in the number of shares they hold because additional shares are issued
  - Size of the pie increases
- Results from:
  - Hiring new employees
  - Raising money
- Founders DON'T sell their own shares when selling equity
  - Company issues new stock
- Professor A owned 20% before seed round; now (s)he owns 18.2%
  - But the value of her / his stake has gone from $1,000 to $400,000
  - This is good!

Definitions

Good Dilution

- Dilution is good if the new shares are sold at a price greater than previous sale
  - Percentage of ownership is less, but the total value of shares owned is greater
  - Smaller slice of a bigger pie
    - Value of ownership stake increases

Bad Dilution

- Dilution is bad if the new shares are sold at a price less than the previous sale
  - Percentage of ownership is less, and the total value of shares owned is less
  - Smaller slice of a smaller pie
    - Value of ownership stake decreases
  - A “cram down”

Definitions

Option

- Right to buy stock at a fixed price for some time in the future
  - Generally personal to the holder (or their estate)
- Two Types under US tax laws:
  - Incentive Stock Option (ISO)
    - Tax treatment much more favorable
    - Only available to employees
  - Non-Qualified Stock Options (NQSO)
- Benefit:
  - You don't have to put out the money to buy the stock till you know it's going to be worth something
    - Or pay any taxes!

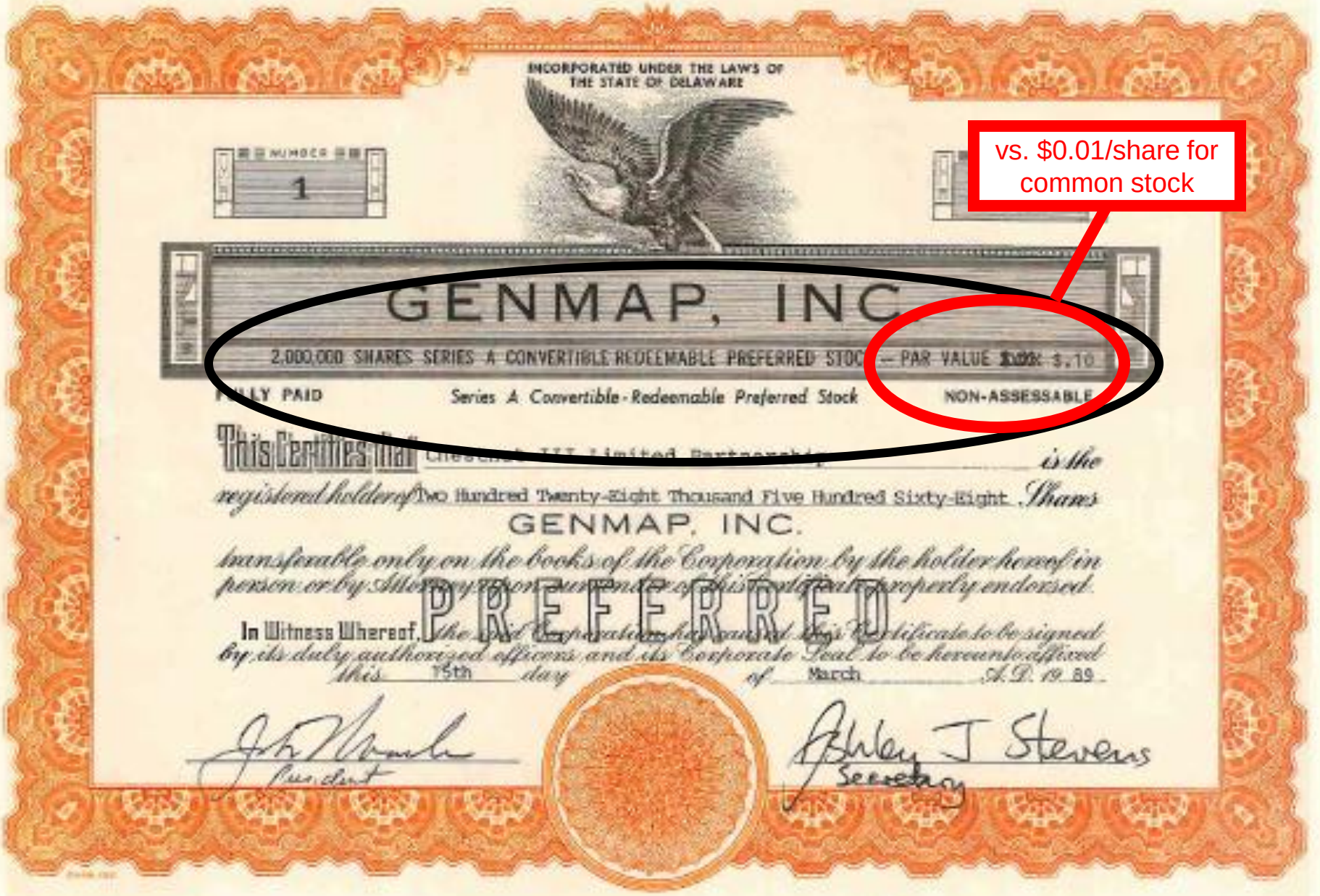
Warrant

- Right to buy stock at a fixed price for some time in the future
  - Can be bought and sold

Definition

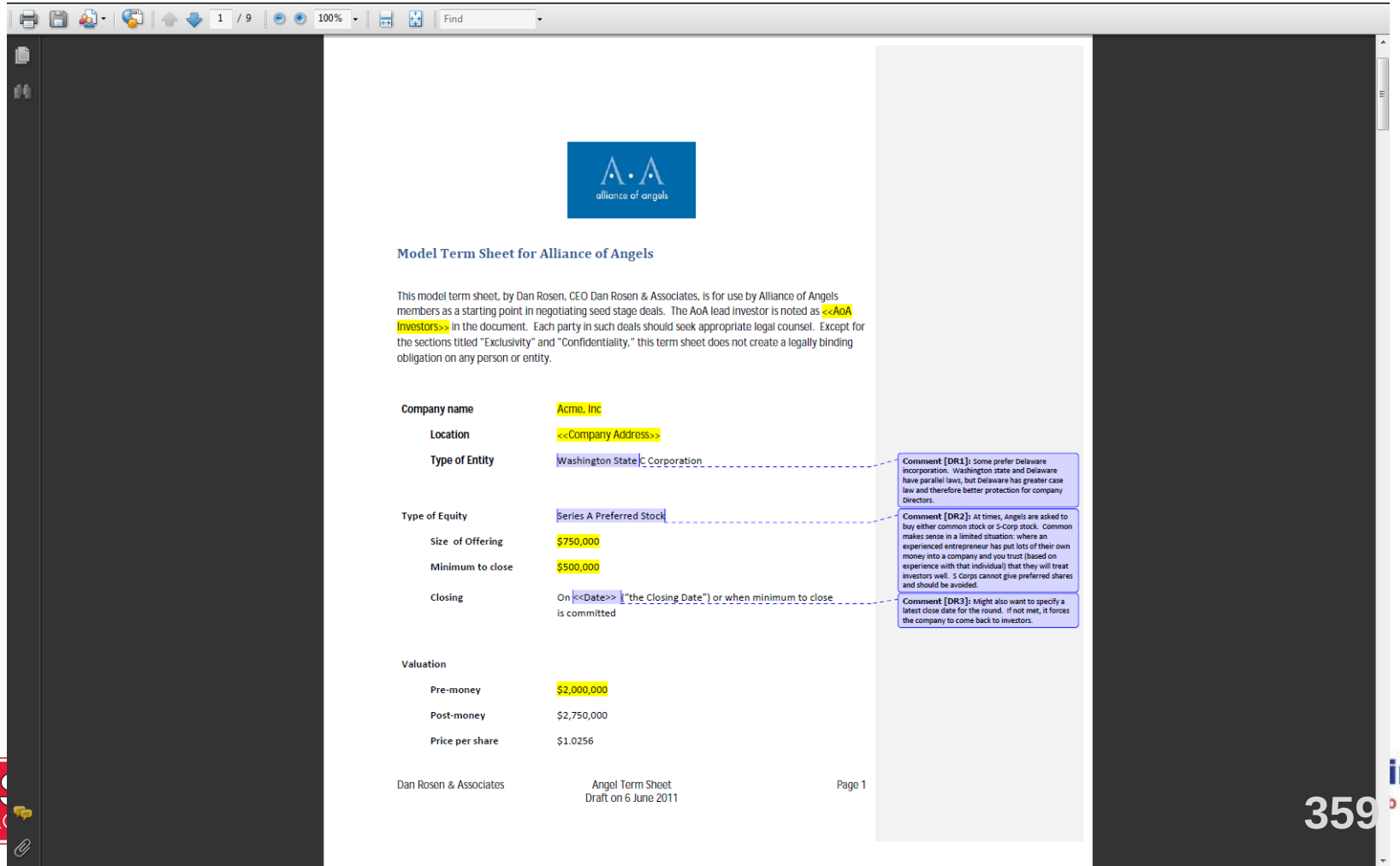
Preferred Stock

- Stock with certain special rights over common stock
- VC's usually invest by buying Participating Convertible Preferred Stock (convertible into Common)
  - Liquidation preference
  - Redemption
  - Optional conversion
  - Automatic conversion
  - Anti-dilution provisions
  - Pre-emptive rights
  - Registration rights
  - Board representation (usually)
  - Dividends
- These Preferences allow the investors to control the company


INCORPORATED UNDER THE LAWS OF
THE STATE OF DELAWARE
NUMBER
1
vs. $0.01/share for common stock
GENMAP, INC.
2,000,000 SHARES SERIES A CONVERTIBLE REDEEMABLE PREFERRED STOCK — PAR VALUE $.10
FULLY PAID
Series A Convertible - Redeemable Preferred Stock
NON-ASSESSABLE
This Certifies that
is the
registered holder of Two Hundred Twenty-Eight Thousand Five Hundred Sixty-Eight Shares
GENMAP, INC.
transferable only on the books of the Corporation by the holder hereof in
person or by Attorney upon surrender of this Certificate properly endorsed.
PREFERRED
In Witness Whereof, the said Corporation has caused this Certificate to be signed
by its duly authorized officers and its Corporate Seal to be hereunto affixed
this 15th day of March A.D. 19 89
President
Secretary

Some resources to learn more

http://www.angelcapitalassociation.org/data/Documents/Resources/1%20-%20Resources/Draft%20Term%20Sheet%20for%20Alliance%20of%20Angels.pdf



alliance of angels

Model Term Sheet for Alliance of Angels

This model term sheet, by Dan Rosen, CEO Dan Rosen & Associates, is for use by Alliance of Angels members as a starting point in negotiating seed stage deals. The AoA lead investor is noted as <<AoA Investors>> in the document. Each party in such deals should seek appropriate legal counsel. Except for the sections titled "Exclusivity" and "Confidentiality," this term sheet does not create a legally binding obligation on any person or entity.

Company name	Acme, Inc
Location	<<Company Address>>
Type of Entity	Washington State C Corporation
Type of Equity	Series A Preferred Stock
Size of Offering	$750,000
Minimum to close	$500,000
Closing	On <<Date>> ("the Closing Date") or when minimum to close is committed
Valuation	
Pre-money	$2,000,000
Post-money	$2,750,000
Price per share	$1.0256

Comment [DR1]: Some prefer Delaware incorporation. Washington state and Delaware have parallel laws, but Delaware has greater case law and therefore better protection for company Directors.

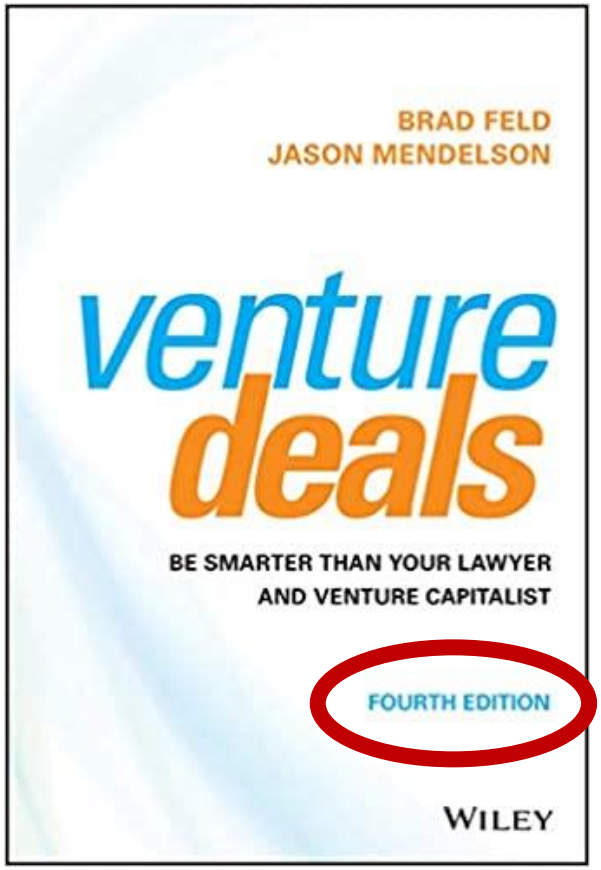
Comment [DR2]: At times, Angels are asked to buy either common stock or S-Corp stock. Common makes sense in a limited situation: where an experienced entrepreneur has put lots of their own money into a company and you trust (based on experience with that individual) that they will treat investors well. S Corps cannot give preferred shares and should be avoided.

Comment [DR3]: Might also want to specify a latest close date for the round. If not met, it forces the company to come back to investors.

Dan Rosen & Associates | Angel Term Sheet Draft on 6 June 2011 | Page 1

Some resources to learn more

Venture Deals: Be Smarter Than Your Lawyer and Venture Capitalist *by Brad Feld and Jason Mendelson*, John Wiley & Sons, Inc. August 2019; ~$30 from Amazon.



Definitions

Series A, Series B, Series C……..

- Successive rounds of Preferred Stock
- Series B usually has precedence over Series A, and so on

Fully Diluted

- Number of shares that will be issued and outstanding when all the options and warrants that have been issued are exercised

Series A Venture Round

- Need to raise $3 million
- Two funds put in $1.5 million each
- 1,000,000 pool of shares created for stock options for future management that will be hired with the proceeds from the financing
- Price $1.00 per share
  - Seed investors show a 25% profit
- Professor's stake now worth $500,000 (+25%)

Series A Venture Round

Price per Share	$1.00						
	Shares			Raised	%		Value
	Common		Series A		I&O	FD	
	Shares	Options					
Professor	500,000				8.7%	7.4%	$500,000
Postdoc A	250,000				4.3%	3.7%	$250,000
Postdoc B	250,000				4.3%	3.7%	$250,000
University	500,000				8.7%	7.4%	$500,000
CEO	1,000,000				17.4%	14.8%	$1,000,000
Seed investors	250,000				4.3%	3.7%	$250,000
Management Pool		1,000,000				14.8%	$1,000,000
VC Fund A			1,500,000	$1,500,000	26.1%	22.2%	$1,500,000
VC Fund B			1,500,000	$1,500,000	26.1%	22.2%	$1,500,000
Total	2,750,000	1,000,000	3,000,000	$3,000,000	100%	100%	$6,750,000

Issued & outstanding	5,750,000
Fully diluted	6,750,000
Raised in this round	$3,000,000
Cumulative raised	$3,225,000
Pre-Money	$3,750,000
Post-Money	$6,750,000

Series B Venture Round

- Need to raise $10 million
- $2.00 per share
  - Sell 5 million shares
- First two funds participate
- New fund leads the round
  - Under NVCA rules, the first two funds can report increased value for Series A investment
    - Helps raise the next fund
- Further increase in management option pool
  - Additional 1 million shares
- Professor's stake now worth $1 million
  - +100%

Series B Venture Round

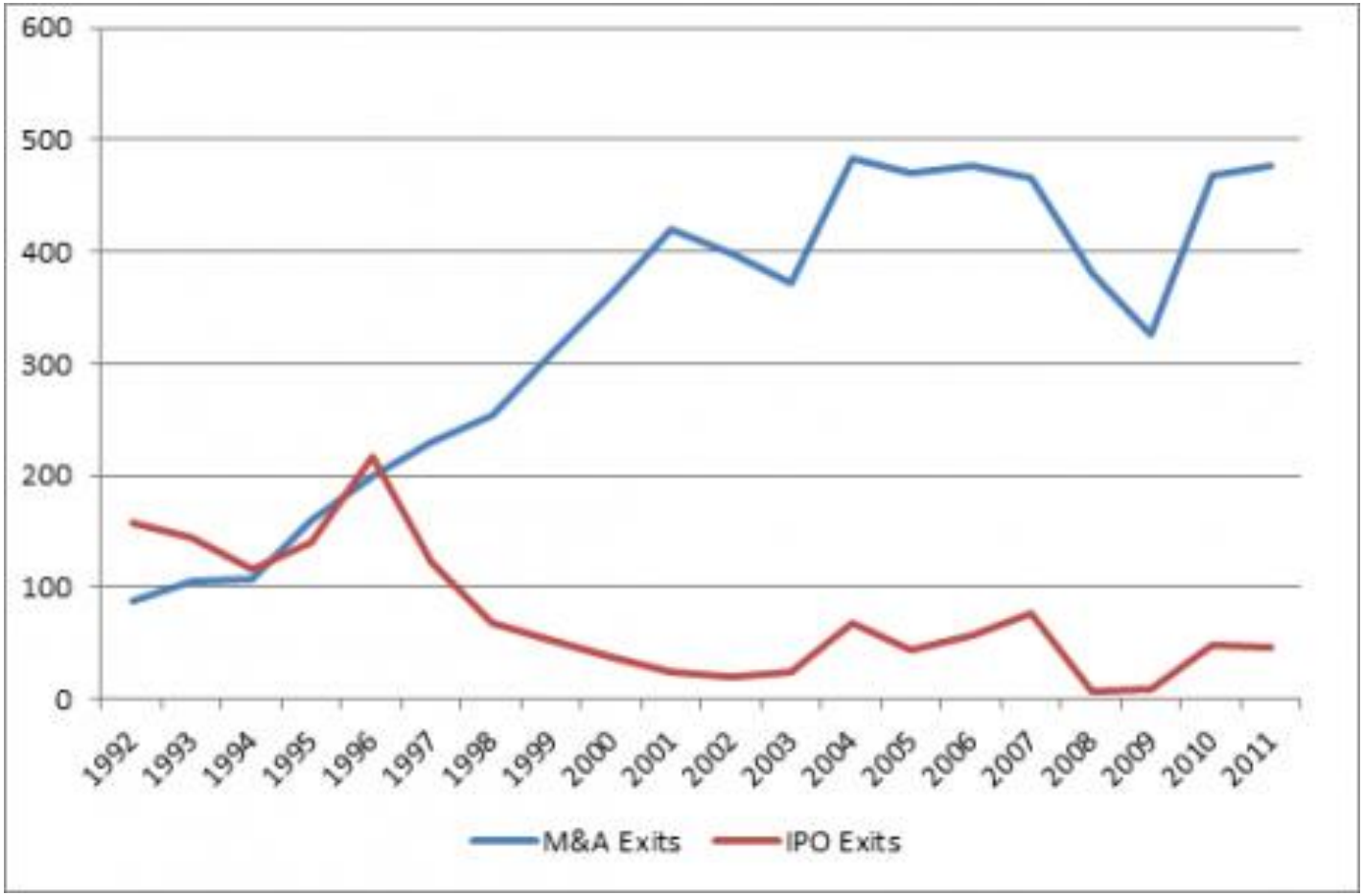
Price per Share	**$2.00**							
	Shares				**Raised**	**%**		**Value**
	Common		**Series A**	**Series B**		**I&O**	**FD**	
	Shares	**Options**						
Professor	500,000					4.7%	3.9%	$1,000,000
Postdoc A	250,000					2.3%	2.0%	$500,000
Postdoc B	250,000					2.3%	2.0%	$500,000
University	500,000					4.7%	3.9%	$1,000,000
CEO	1,000,000					9.3%	7.8%	$2,000,000
Seed investors	250,000					2.3%	2.0%	$500,000
Management Pool		2,000,000					15.7%	$4,000,000
VC Fund A			1,500,000	1,500,000	$3,000,000	27.9%	23.5%	$6,000,000
VC Fund B			1,500,000	1,500,000	$3,000,000	27.9%	23.5%	$6,000,000
VC Fund C				2,000,000	$4,000,000	18.6%	15.7%	$4,000,000
Total	2,750,000	2,000,000	3,000,000	5,000,000	$10,000,000	100%	100%	$25,500,000

Issued and outstanding	10,750,000
Fully diluted	12,750,000
Raised in this round	$10,000,000
Cumulative raised	$13,225,000
Pre-Money	$15,500,000
Post-Money	$25,500,000

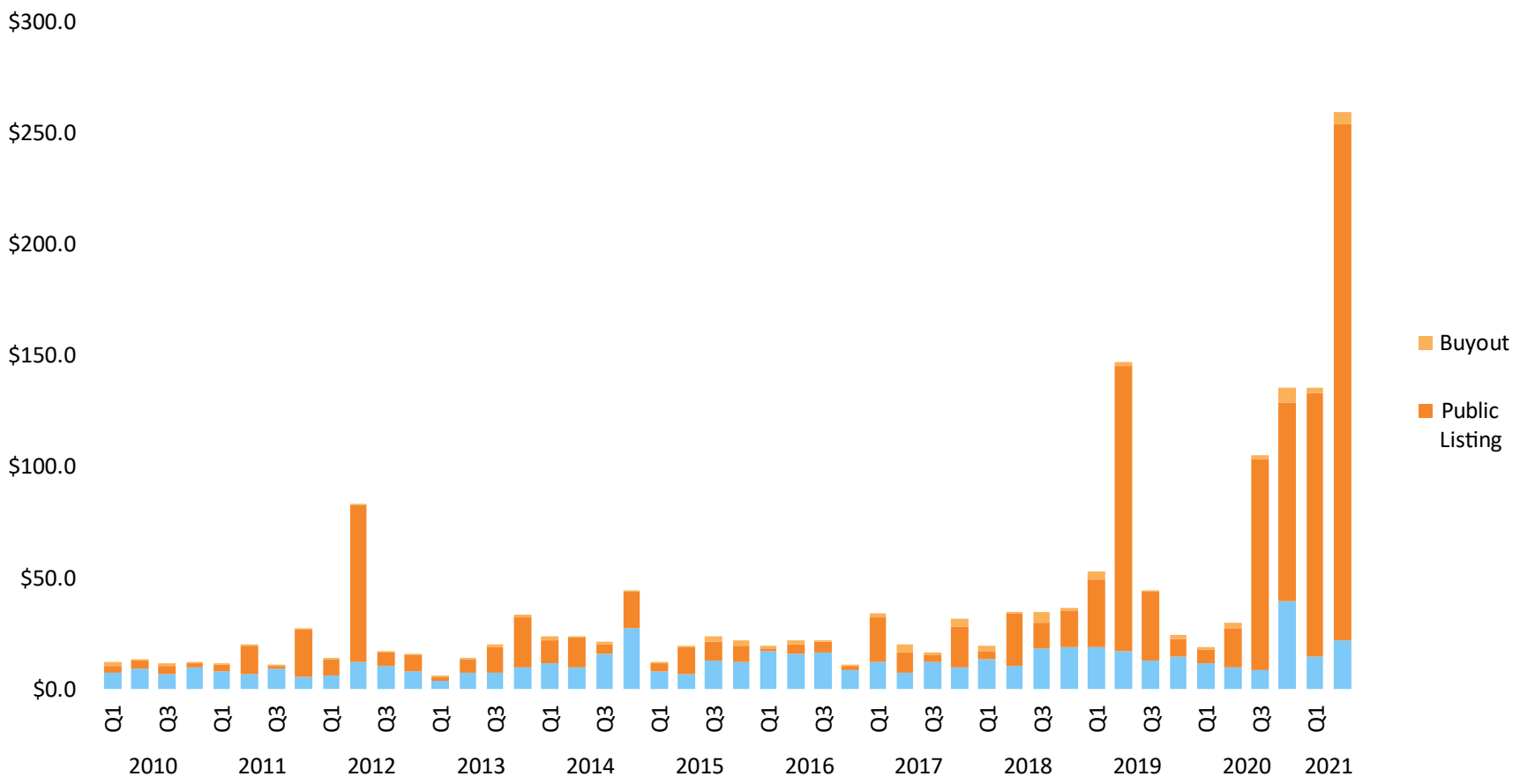
The Exit

- IPO
- Acquisition
  - Cash
  - Stock
    - Publicly traded
    - Privately held

The Exit



The Exit



Initial Public Offering

- Company is ready to sell stock to the public
- Sells 8 million shares to the public at $8.00 per share
- Professor's stake now worth $4,000,000
  - +300%

AMENDMENT NO. 6
TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

TALECRIS BIOTHERAPEUTICS HOLDINGS CORP.
(Exact name of registrant as specified in its charter)

DELAWARE	2834	20-2533768
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

P.O. Box 110526
4101 Research Commons
79 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
(919) 316-6300
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

LAWRENCE D. STERN
Chairman and Chief Executive Officer
TALECRIS BIOTHERAPEUTICS HOLDINGS CORP.
P.O. Box 110526
4101 Research Commons
79 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
(919) 316-6300
(Name, address, including zip code, and telephone number, including area code, of agent for service)

---

with copies to:

GERARD S. DIFIORE
ARON IZOWER
REED SMITH LLP
599 Lexington Avenue
New York, New York 10022
(212) 521-5400
(212) 521-5450 (facsimile)

JOHN F. GAITHER, Jr.
Executive Vice President,
General Counsel and Secretary
TALECRIS BIOTHERAPEUTICS
HOLDINGS CORP.
P.O. Box 110526
4101 Research Commons
79 T.W. Alexander Drive
Research Triangle Park,
North Carolina 27709
(919) 316-6300
(253) 390-6623 (facsimile)

GLEN T. SCHLEYER
SULLIVAN & CROMWELL LLP
125 Broad Street
New York, New York 10004
(212) 558-4000
(212) 558-3588 (facsimile)

Approximate date of commencement of proposed sale to the public:
As soon as practicable after this Registration Statement is declared effective.

g registered on this Form are offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act") please check the following box. o

ster additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

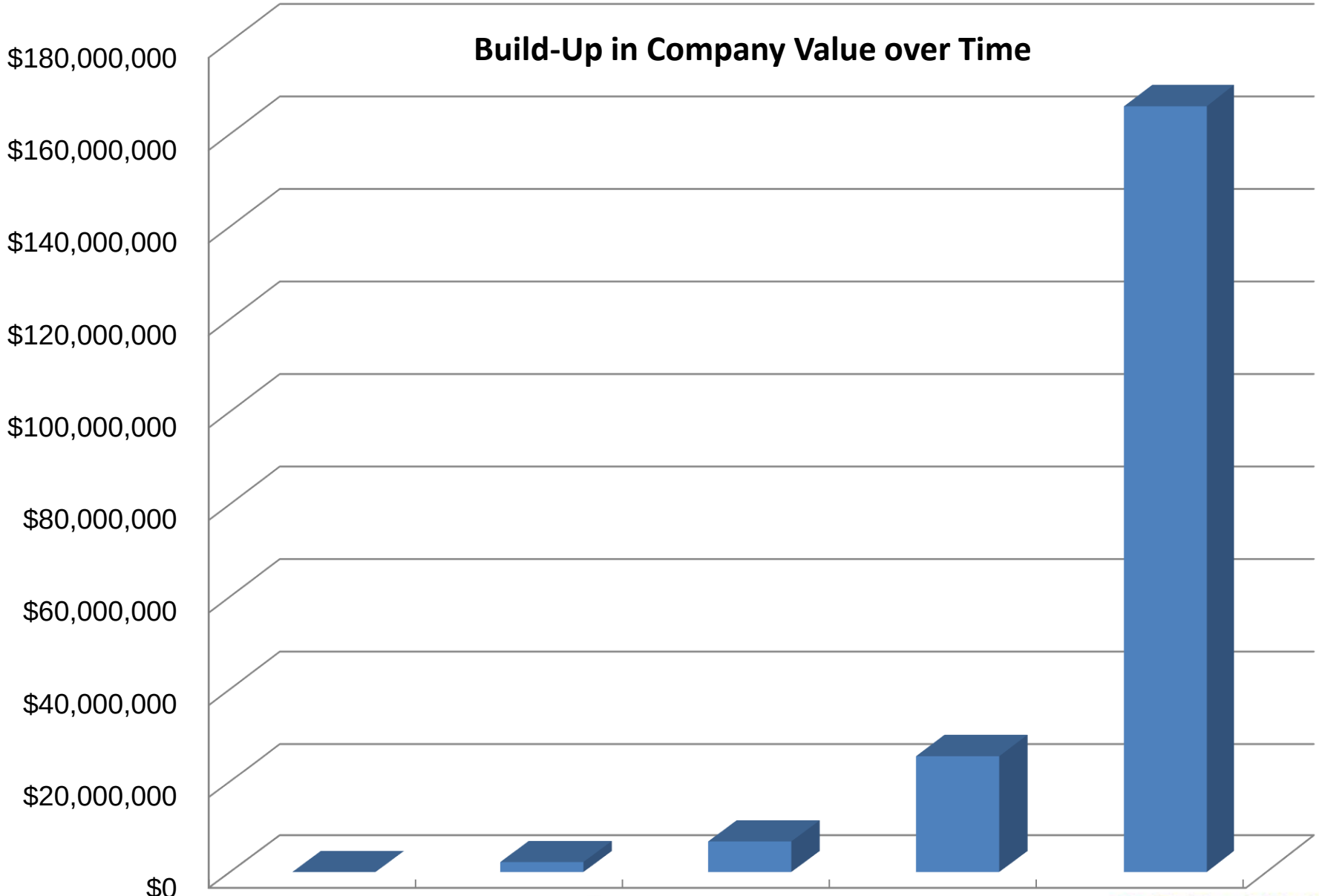
ve amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

IPO

Price per Share		$8.00			
	Shares Common Shares	Raised	% I&O	% FD	Value
Professor	500,000		2.4%	2.4%	$4,000,000
Postdoc A	250,000		1.2%	1.2%	$2,000,000
Postdoc B	250,000		1.2%	1.2%	$2,000,000
University	500,000		2.4%	2.4%	$4,000,000
CEO	1,000,000		4.8%	4.8%	$8,000,000
Seed investors	250,000		1.2%	1.2%	$2,000,000
Management Pool	2,000,000		9.6%	9.6%	$16,000,000
VC Fund A	3,000,000		14.5%	14.5%	$24,000,000
VC Fund B	3,000,000		14.5%	14.5%	$24,000,000
VC Fund C	2,000,000		9.6%	9.6%	$16,000,000
Public Investors	8,000,000	$64,000,000	38.6%	38.6%	$64,000,000
Total	20,750,000	$64,000,000	100%	100%	$166,000,000

Issued & outstanding	20,750,000
Fully diluted	20,750,000
Raised in this round	$64,000,000
Cumulative raised	$77,225,000

Pre-Money	$102,000,000
Post-Money	$166,000,000



Definitions

Registered Stock

Stock that has been issued under a registration statement approved by the SEC and can be freely sold to the public

Unregistered Stock

Stock that has been sold not in connection with a registration statement approved by the SEC; cannot be sold in the public markets

Life After the IPO

- Can’t immediately sell stock
- Underwriters will normally impose a 180 day lock-up on all pre-IPO stock
  - Once saw a European IPO with a 1 year lock-up
- Remaining stock needs to be registered to sell
  - Can sell limited amounts under Rule 144

"The transfer of the shares of stock represented by this Certificate is restricted under the terms of a Co-Sale Agreement dated as of March 15, 1989, a copy of which is on file at the office of the Company."

For Value Received, ____ *hereby sell, assign and transfer unto*

_____ *Shares*

represented by the within Certificate, and do hereby irrevocably constitute and appoint

_____ *Attorney*

to transfer the said Shares on the books of the within named Corporation with full power of substitution in the premises.

Dated _____ *19*

In presence of

_____

The Dark Side – Things Go Wrong

- Company does not meet its milestones for Series B financing
- Series B price is $0.60 per share, not $2.00 per share
  - A “Down Round”
  - Can’t bring in Fund C
    - Only existing investors will participate
- Now needs $11 million to get to IPO
  - $1 million to get back on track
  - $10 million to go to market
- Has to sell 18,333,333 shares to raise $11 million, not 2,000,000 shares
- Professors stake now worth $300,000
  - Down 33% (vs up 400% in happy scenario)
- Major shift in ownership from common to preferred

Series B Venture Round

Price per Share	**$0.60**							
	Shares				**Raised**	**%**		**Value**
	Common		**Series A**	**Series B**		**I&O**	**FD**	
	Shares	**Options**						
Professor	500,000					2.2%	2.0%	$300,000
Postdoc A	250,000					1.1%	1.0%	$150,000
Postdoc B	250,000					1.1%	1.0%	$150,000
University	500,000					2.2%	2.0%	$300,000
CEO	1,000,000					4.3%	4.0%	$600,000
Seed investors	250,000					1.1%	1.0%	$150,000
Management Pool		2,000,000					8.0%	$1,200,000
VC Fund A			1,000,000	9,166,667	$ 5,500,000	44.0%	40.5%	$6,100,000
VC Fund B			1,000,000	9,166,667	$ 5,500,000	44.0%	40.5%	$6,100,000
Total	2,750,000	2,000,000	2,000,000	18,333,333	$ 11,000,000	100%	100%	$15,050,000

Issued $ outstanding	23,083,333
Fully diluted	25,083,333
Raised in this round	$11,000,000
Cumulative raised	$14,225,000
Pre-Money	$4,050,000
Post-Money	$15,050,000

IPO with Reverse Split

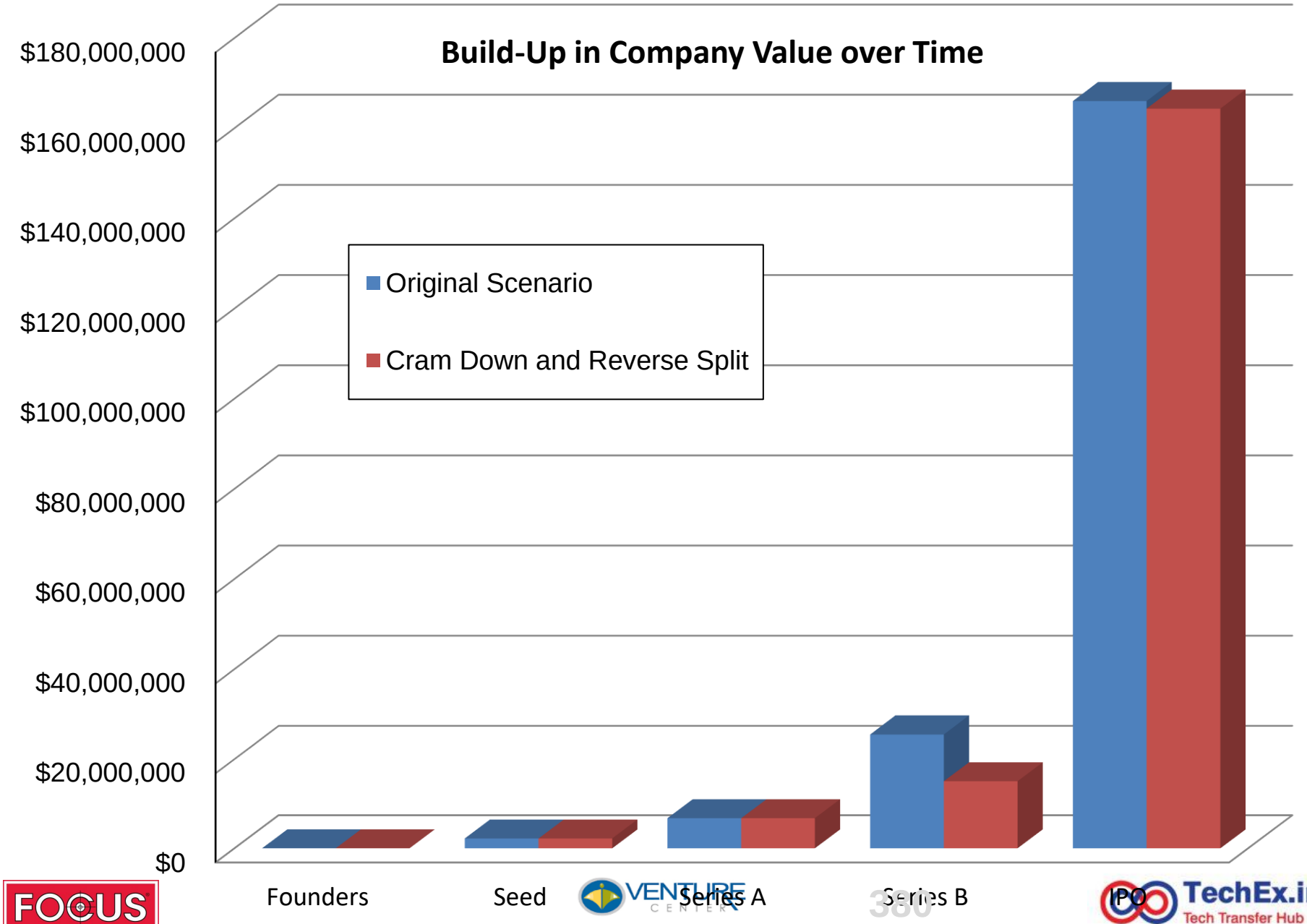
- Because of Cram Down, investment bankers may decide Company needs to reduce number of shares outstanding
  - 25,083,333 FD shares vs. 12,750,000
- Reverse split, 1 for 2
  - Gets back close to 13,000,000 shares
- Professor's stake now worth $2,000,000, +667%

Example:

- Acusphere (MIT / Langer) did Series A, B, C, D, E, F, G, H, I and J financings!
  - Founded 1993
  - Perflubutane polymer microspheres for detection of coronary artery disease
    - Never got anything approved anywhere
- 1 for 10 reverse split prior to IPO
  - $14/share, 2003
  - And it did **ANOTHER** 1 for 10 reverse split in 2012
    - Seems to finally have quietly died in 2012 – 19 years!

IPO with Reverse Split

Price per Share	$8.00					
Reverse Split	1 for 2				Original Scenario	
	Shares Common Shares	Raised	% I&O	Value	Value	Diff
Professor	250,000		1.2%	$2,000,000	$4,000,000	($2,000,000)
Postdoc A	125,000		0.6%	$1,000,000	$2,000,000	($1,000,000)
Postdoc B	125,000		0.6%	$1,000,000	$2,000,000	($1,000,000)
University	250,000		1.2%	$2,000,000	$4,000,000	($2,000,000)
CEO	500,000		2.4%	$4,000,000	$8,000,000	($4,000,000)
Seed investors	125,000		0.6%	$1,000,000	$2,000,000	($1,000,000)
Management Pool	1,000,000		4.9%	$8,000,000	$16,000,000	($8,000,000)
VC Fund A	5,083,333		24.7%	$40,666,667	$24,000,000	$16,666,667
VC Fund B	5,083,333		24.7%	$40,666,667	$24,000,000	$16,666,667
VC Fund C					$16,000,000	($16,000,000)
Public Investors	8,000,000	$64,000,000	38.9%	$64,000,000	$64,000,000	$0
Total	20,541,667	$64,000,000	100%	$164,333,333	$166,000,000	($1,666,667)
Issued & outstanding	20,541,667				$20,750,000	($208,333)
Fully diluted	20,541,667				$20,750,000	($208,333)
Raised in this round	$64,000,000				$64,000,000	$0
Cumulative raised	$78,225,000				$77,210,000	$1,000,000
Pre-Money	$100,333,333				$102,000,000	($1,666,667)
Post-Money	$164,333,333				$166,000,000	($1,666,667)



Acquisition

- The alternative to IPO
- Benefit
  - Immediate liquidity
- The Dark Side
  - From the Entrepreneurs' and Managements' perspectives
  - Liquidation Preferences

Definition

Liquidation Preference

- Payment received by preferred stock holder on liquidation or acquisition of the company
  - Usually at least equal to the original investment
  - Can be multiples of the original investment

Participating Preferred Stock

- After payment of the preferences, remaining funds are distributed *pro rata* to **ALL** shareholders
  - Including preferred
  - A double dip
    - VC's love acquisitions

Acquisition with Liquidation Preferences

Acquisition Price	**$91,800,000**			
Per share	**$7.2**			
Liquid. Pref.			**Price**	
	Series A	**1**	**x**	**$ 1.00**
	Series B	**1**	**x**	**$ 2.00**

	Shares				%			Proceeds				
	Common		Series A	Series B	I&O	FD	Preferences	Balance	Total	IPO	Δ	%
	Shares	Options										
Professor	500,000				4.7%	3.9%		$3,090,196	$3,090,196	$4,000,000	($909,804)	77.3%
Postdoc A	250,000				2.3%	2.0%		$1,545,098	$1,545,098	$2,000,000	($454,902)	77.3%
Postdoc B	250,000				2.3%	2.0%		$1,545,098	$1,545,098	$2,000,000	($454,902)	77.3%
University	500,000				4.7%	3.9%		$3,090,196	$3,090,196	$4,000,000	($909,804)	77.3%
CEO	1,000,000				9.3%	7.8%		$6,180,392	$6,180,392	$8,000,000	($1,819,608)	77.3%
Seed investors	250,000				2.3%	2.0%		$1,545,098	$1,545,098	$2,000,000	($454,902)	77.3%
Mgmt Pool		2,000,000				15.7%		$12,360,784	$12,360,784	$16,000,000	($3,639,216)	77.3%
VC Fund A			1,500,000	1,500,000	27.9%	23.5%	$4,500,000	$18,541,176	$23,041,176	$24,000,000	($958,824)	96.0%
VC Fund B			1,500,000	1,500,000	27.9%	23.5%	$4,500,000	$18,541,176	$23,041,176	$24,000,000	($958,824)	96.0%
VC Fund C				2,000,000	18.6%	15.7%	$4,000,000	$12,360,784	$16,360,784	$16,000,000	$360,784	102.3%
Total	2,750,000	2,000,000	3,000,000	5,000,000	100%	100%	$13,000,000	$78,800,000	$91,800,000	$102,000,000	($10,200,000)	90.0%

Issued & Outstanding	10,750,000
Fully Diluted	12,750,000

Acquisition with Liquidation Preferences after Cram Down

Acquisition Price	**$91,800,000**			
Per share	**$7.2**			
Liquidation Preferences				
Series A	**1**	**x**	**$**	**1.00**
Series B	**3**	**x**	**$**	**0.60**

	Shares				%			Proceeds				
	Common		Series A	Series B	I&O	FD	Preferences	Balance	Total	Base Case	Δ	%
	Shares	Options										
Professor A	500,000				2.2%	2.0%		$1,132,226	$1,132,226	$3,090,196	($1,957,970)	36.6%
Postdoc B	250,000				1.1%	1.0%		$566,113	$566,113	$1,545,098	($978,985)	36.6%
Postdoc C	250,000				1.1%	1.0%		$566,113	$566,113	$1,545,098	($978,985)	36.6%
University	500,000				2.2%	2.0%		$1,132,226	$1,132,226	$3,090,196	($1,957,970)	36.6%
CEO	1,000,000				4.3%	4.0%		$2,264,452	$2,264,452	$6,180,392	($3,915,940)	36.6%
Seed investors	250,000				1.1%	1.0%		$566,113	$566,113	$1,545,098	($978,985)	36.6%
Management Pool		2,000,000				8.0%		$4,528,904	$4,528,904	$12,360,784	($7,831,881)	36.6%
VC Fund A			1,000,000	9,166,667	44.0%	40.5%	$17,500,000	$23,021,927	$40,521,927	$23,041,176	$17,480,750	175.9%
VC Fund B			1,000,000	9,166,667	44.0%	40.5%	$17,500,000	$23,021,927	$40,521,927	$23,041,176	$17,480,750	175.9%
VC Fund C										$16,360,784	($16,360,784)	
Total	2,750,000	2,000,000	2,000,000	18,333,333	100%	100%	$35,000,000	$56,800,000	$91,800,000	$91,800,000	$0	100.0%

Issued and outstanding	23,083,333
Fully diluted	25,083,333

Non-Dilutive Funding

- There are great benefits to founders and management if grants can be used to fund early stage development
  - Instead of investment capital
- Sources:
  - SBIR's
  - Other Federal sources
  - Corporate partners
  - Philanthropies
- This is referred to as "Non-Dilutive Funding" because NewCo doesn't have to issue stock to get the money
  - No dilution to existing shareholders

Non-Dilutive Funding

- Assume that our NewCo can get grants to replace its Series A investment
- Analytical approach:
  - Eliminate Series A shares from Cap Table
    - Results in lower Pre-Money for Series B
  - But company is at same stage of development
    - Therefore it should have same pre-money valuation for Series B
  - Using Goal Seek, set Pre-Money to $15.5 million by varying Share Price
    - Share Price increases from $2.00 to $3.26 / share
      - At the higher price, fewer shares have to be sold in Series B
        - 3.1 million vs 5 million
        - Even less dilution to existing shareholders
    - Founders', Managements and Seed Investors' stakes increase in value by ~63%
      - VC's make less but have invested less

Series B Round With Non-Dilutive Funding Instead of Series A

Price per Share	$3.26									With Series A			
	Shares				Raised	%		Value		%		Value	Δ
	Common		Series A	Series B		I&O	FD			I&O	FD		
	Shares	Options											
Professor	500,000					8.6%	6.4%	$1,631,579		4.7%	3.9%	$1,000,000	$631,579
Postdoc A	250,000					4.3%	3.2%	$815,789		2.3%	2.0%	$500,000	$315,789
Postdoc B	250,000					4.3%	3.2%	$815,789		2.3%	2.0%	$500,000	$315,789
University	500,000					8.6%	6.4%	$1,631,579		4.7%	3.9%	$1,000,000	$631,579
CEO	1,000,000					17.2%	12.8%	$3,263,158		9.3%	7.8%	$2,000,000	$1,263,158
Seed investors	250,000					4.3%	3.2%	$815,789		2.3%	2.0%	$500,000	$315,789
Management Pool		2,000,000					25.6%	$6,526,316			15.7%	$4,000,000	$2,526,316
VC Fund A				919,355	$3,000,000	15.8%	11.8%	$3,000,000		27.9%	23.5%	$6,000,000	($3,000,000)
VC Fund B				919,355	$3,000,000	15.8%	11.8%	$3,000,000		27.9%	23.5%	$6,000,000	($3,000,000)
VC Fund C				1,225,806	$4,000,000	21.1%	15.7%	$4,000,000		18.6%	15.7%	$4,000,000	$0
Total	2,750,000	2,000,000	0	3,064,516	$10,000,000	100%	100%	$25,500,000				$25,500,000	
Issued and outstanding	5,814,516												
Fully diluted	7,814,516												
Raised in this round	$10,000,000												
Cumulative raised	$13,225,000												
Pre-Money	$15,500,000												
Post-Money	$25,500,000												

Non-Dilutive Funding

- Company is now ready for IPO
- No Series A and lower number of Series B shares results in lower pre-money
  - Again, company is at the same stage and so should be worth the same
  - Using Goal Seek, set Pre-Money to $102 million by varying the Share Price
    - Share Price increases from $8.00 to $13.05 / share
  - Company no longer needs to sell 8 million shares to raise $64 million
    - Only needs to sell 4.9 million shares
  - Founders', Management's and Seed Investors' stakes increase in value by ~63%
    - VC's make less but have invested less

IPO With Non-Dilutive Funding Instead of Series A

Price per Share	$13.05							With Series A		
	Shares	Raised	%		Value		%		Value	Δ
	Common Shares		I&O	FD			I&O	FD		
Professor	500,000		3.9%	3.9%	$6,526,316		2.4%	2.4%	$4,000,000	$2,526,316
Postdoc A	250,000		2.0%	2.0%	$3,263,158		1.2%	1.2%	$2,000,000	$1,263,158
Postdoc B	250,000		2.0%	2.0%	$3,263,158		1.2%	1.2%	$2,000,000	$1,263,158
University	500,000		3.9%	3.9%	$6,526,316		2.4%	2.4%	$4,000,000	$2,526,316
CEO	1,000,000		7.9%	7.9%	$13,052,632		4.8%	4.8%	$8,000,000	$5,052,632
Seed investors	250,000		2.0%	2.0%	$3,263,158		1.2%	1.2%	$2,000,000	$1,263,158
Management Pool	2,000,000		15.7%	15.7%	$26,105,263		9.6%	9.6%	$16,000,000	$10,105,263
VC Fund A	919,355		7.2%	7.2%	$12,000,000		14.5%	14.5%	$24,000,000	($12,000,000)
VC Fund B	919,355		7.2%	7.2%	$12,000,000		14.5%	14.5%	$24,000,000	($12,000,000)
VC Fund C	1,225,806		9.6%	9.6%	$16,000,000		9.6%	9.6%	$16,000,000	$0
Public Investors	4,903,226	$64,000,000	38.6%	38.6%	$64,000,000		38.6%	38.6%	$64,000,000	$0
Total	12,717,742	$64,000,000	100%	100%	$166,000,000		100%	100%	$166,000,000	
Issued and outstanding	12,717,742									
Fully diluted	12,717,742									
Raised in this round	$64,000,000									
Cumulative raised	$77,225,000									
Pre-Money	$102,000,000									
Post-Money	$166,000,000									

Venture Debt

- Another non-dilutive source of financing
- Start-up companies balance sheets don’tsupport debt financing
  - Inadequate assets and cash flow
    - Hence the VC market
- After ~Series C, some specialized banks and other financial institutions may be prepared to lend
  - Up to 30% of last funding round
  - 1-4 year term
    - Interest-only for 1-2 years
  - High interest rate
    - Prime +3-4%
  - Warrants for 5-20% of loan amount
- SVB was a major source of venture debt financing

Venture Leasing

- Another non-dilutive source of financing
- Similar to Venture Debt
  - Leasing company gets warrant coverage ~10% of lease value

Anti-Dilution Negotiating Model

- In base case, the university has been treated as a co-founder
  - Same ownership stake as the Prof.
- The dominant U.S. negotiating model is anti-dilution:
  - "Give me 5% [or 10%] but keep me at 5% [or 10%] till X million has been raised
- Let's model two negotiations:
  - 10% with protection till $3 million has been raised
  - 5% with protection till $5 million has been raised

Cap Table after Founders Round, 10% Anti-Dilution Protection till $3 million Raised

Price per Share	**$0.01**					
	Shares	**Raised**	**%**		**Value**	
Professor	**500,000**	**$5,000**	**22.5%**		**$5,000**	
Postdoc A	**250,000**	**$2,500**	**11.3%**		**$2,500**	
Postdoc B	**250,000**	**$2,500**	**11.3%**		**$2,500**	
University	**222,000**	**$2,220**	**10.0%**		**$2,220**	
CEO	**1,000,000**	**$10,000**	**45.0%**		**$10,000**	
Total	**2,222,000**	**$22,220**	**100%**		**$22,220**	
Issued and outstanding	**2,222,000**					
Fully diluted	**2,222,000**					
Raised in this round	**$22,220**					
Cumulative raised	**$22,220**					

Cap Table after Seed Round, 10% Anti-Dilution Protection till $3 million Raised

Price per Share	$0.80				
	Shares	**Raised**	**%**		**Value**
Professor	500,000		20%		$400,000
Postdoc A	250,000		10%		$200,000
Postdoc B	250,000		10%		$200,000
University	222,000		8.9%		$199,200
Anti-Dilution Shares	27,000	$21,600	1.1%		$221,600
CEO	1,000,000		40%		$800,000
Seed investors	250,000	$200,000	10%		$200,000
Total	2,499,000	$221,600	100%		$2,220,800
Issued and outstanding	2,499,000				
Fully diluted	2,499,000				
Raised in this round	$221,600				
Cumulative raised	$243,820				
Pre-Money	$1,999,200				
Post-Money	$2,220,800				

Cap Table after Series A Round, 10% Anti-Dilution Protection till $3 million Raised

Price per Share	$1.00						
	Shares			Raised	%		Value
	Common		Series A		I&O	FD	
	Shares	Options					
Professor	500,000				8.4%	7.2%	$500,000
Postdoc A	250,000				4.2%	3.6%	$250,000
Postdoc B	250,000				4.2%	3.6%	$250,000
University	249,000				4.2%	3.6%	$694,000
Anti-Dilution Shares	445,000				7.5%	6.4%	$695,000
CEO	1,000,000				16.8%	14.4%	$1,000,000
Seed investors	250,000				4.2%	3.6%	$250,000
Management Pool		1,000,000				14%	$1,000,000
VC Fund A			1,500,000	$1,500,000	25%	22%	$1,500,000
VC Fund B			1,500,000	$1,500,000	25%	22%	$1,500,000
Total	2,944,000	1,000,000	3,000,000	$3,000,000	100%	100%	$7,639,000
Issued and outstanding	5,944,000						
Fully diluted	6,944,000						
Raised in this round	$3,000,000						
Cumulative raised	$3,225,000						
Pre-Money	$4,639,000						
Post-Money	$7,639,000						

Cap Table after Founders Round, 5% Anti-Dilution Protection till $5 million Raised						
Price per Share	$0.01					
	Shares	Raised	%		Value	
Professor	500,000	$5,000	23.7%		$5,000	
Postdoc A	250,000	$2,500	11.9%		$2,500	
Postdoc B	250,000	$2,500	11.9%		$2,500	
University	106,000	$1,060	5.0%		$1,060	
CEO	1,000,000	$10,000	47.5%		$10,000	
Total	2,106,000	$21,060	100%		$21,060	
Issued and outstanding	2,106,000					
Fully diluted	2,106,000					
Raised in this round	$21,060					
Cumulative raised	$21,060					

Cap Table after Seed Round, 5% Anti-Dilution Protection till $5 million Raised

Price per Share	**$0.80**				
	Shares	**Raised**	**%**		**Value**
Professor	**500,000**		**21.1%**		**$400,000**
Postdoc A	**250,000**		**10.6%**		**$200,000**
Postdoc B	**250,000**		**10.6%**		**$200,000**
University	**106,000**		**4.5%**		**$84,800**
Anti-Dilution Shares	**12,000**		**0.5%**		**$809,600**
CEO	**1,000,000**		**42.2%**		**$1,000,000**
Seed investors	**250,000**	**$200,000**	**10.6%**		**$200,000**
Total	**2,368,000**	**$200,000**	**100%**		**$2,894,400**
Issued and outstanding	**2,368,000**				
Fully diluted	**2,368,000**				
Raised in this round	**$200,000**				
Cumulative raised	**$222,220**				
Pre-Money	**$2,694,400**				
Post-Money	**$2,894,400**				

Cap Table after Series A Round, 5% Anti-Dilution Protection till $5 million Raised

Price per Share	$1.00						
	Shares			Raised	%		Value
	Common		Series A		I&O	FD	
	Shares	Options					
Professor	500,000				9%	8%	$500,000
Postdoc A	250,000				4%	4%	$250,000
Postdoc B	250,000				4%	4%	$250,000
University	118,000				2%	2%	$118,000
Anti-Dilution Shares	200,000				3.6%	3.0%	$1,200,000
CEO	1,000,000				18.0%	15.2%	$1,250,000
Seed investors	250,000				4%	4%	$250,000
0							
Management Pool		1,000,000				15%	$1,000,000
VC Fund A			1,500,000	$1,500,000	27%	23%	$1,500,000
VC Fund B			1,500,000	$1,500,000	27%	23%	$1,500,000
Total	2,568,000	1,000,000	3,000,000	$3,000,000	100%	100%	$7,818,000
Issued and outstanding	5,568,000						
Fully diluted	6,568,000						
Raised in this round	$3,000,000						
Cumulative raised	$3,225,000						
Pre-Money	$4,818,000						
Post-Money	$7,818,000						

Cap Table after Series B Round, 5% Anti-Dilution Protection till $5 million Raised

Price per Share	$2.00							
	Shares				Raised	%		Value
	Common		Series A	Series B*		I&O	FD	
	Shares	Options						
Professor	500,000					4.7%	3.9%	$1,000,000
Postdoc A	250,000					2.3%	2.0%	$500,000
Postdoc B	250,000					2.3%	2.0%	$500,000
University	318,000					3.0%	2.5%	$636,000
Anti-Dilution Shares	110,000					1.0%	0.9%	$720,000
CEO	1,000,000					9.4%	7.9%	$2,220,000
Seed Investors	250,000					2.3%	2.0%	$500,000
Management Pool		2,000,000					16%	$4,000,000
VC Fund A			1,500,000	1,500,000	$ 3,000,000	14%	12%	$3,000,000
VC Fund B			1,500,000	1,500,000	$ 3,000,000	14%	12%	$3,000,000
VC Fund C				2,000,000	$ 4,000,000	19%	16%	$4,000,000
Total	2,678,000	2,000,000	3,000,000	5,000,000	$ 10,000,000	72%	76%	$20,076,000
Issued and outstanding	10,678,000		* Round split into 2 segments -- $2 million gets total raised to $5 million					
Fully diluted	12,678,000		at which point University's antidilution shares are calculated.					
Raised in this round	$10,000,000		Remaining $8 million takes University down to 3.4% at end of Series B					
Cumulative raised	$10,225,000							
Pre-Money	$10,076,000							
Post-Money	$20,076,000							

Comparison of University Shareholdings Under 3 Negotiating Models

Shares held by Univ after	Negotiating Model: Co-Founder	Anti-Dilution		
	20%	10%/$3 mm	5%/$5mm	
Founders	500,000	222,000	106,000	
Seed	500,000	249,000	118,000	
Series A	500,000	694,000	318,000	
Series B	500,000	694,000	428,000	*

* Round split into 2 segments -- $2 million gets total raised to $5 million

Conclusions on Anti-Dilution Negotiating Models

- Outcome is close to or better than Co-Founder / Fair Share models
  - 10% / $3 million is 39% better than 20%
  - 5% / 5 million is only 14% worse than 20%
- 5% is a much easier sell than 20%
  - Few faculty have the insight to do the analysis
- Both numbers – the percentage and the anti-dilution limit – are equally important
- Despite what people will try to tell you, VC's will invest as long as:
  - They can see when the anti-dilution ends
  - The percentage being protected is reasonable
- Do not allow non-dilutive funding to count towards the limit
  - "What part of 'non-dilutive' don't you understand?"

How Do You Know What to Sell a Company for?

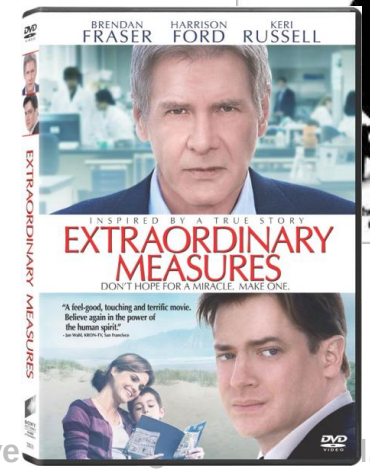
- Two main bases for high tech companies
- If public, market cap plus a premium
- If private -- 
  i.e., X times its sales
- Every industry has its “X”
  - Find three or four recent transactions in the same space and calculate
- Pharmaceuticals:
  - X=5
    - E.g., Genzyme’s sales were $4 billion
      - Sanofi paid $20 billion

And if this is all too complicated……

- Don't bother to take equity at all
  - Who cares about owning stock?
    - What we really want is to be able to sell the stock
  - So ask for an Exit Fee instead
  - Paid if:
    - Change of control (acquisition)
    - IPO
  - 1 – 3% of amount raised (acquisition) / pre-money value (IPO)
- Benefits:
  - Simpler, cleaner
  - May help with CoI
  - No issues of Board representation
- Examples:
  - NIH
  - U. of Kansa Swift Startup License (kuic.ku.edu/swift-startup-license)

Two Great Movies About Start-Ups

- Startup.com
  - Two guys start a dot.com. Filmed in real time as it was happening
  - Truly ugly buy-out of a vested founder who didn't join the company
    - Plus a whole lot of other highly emotional stuff
- Extraordinary Measures
  - The very thinly disguised accoun evelopment of Lumizyme. Harrison Ford



For More Information

- *The Art of the Cap Table* Ashley Stevens, *Journal of Commercial Biotechnology* (2012) 18, 83–97. doi: 10.5912/jcb.522;
  - The spreadsheet that this talk and the article were based on.
- *Intellectual Property Valuation Manual For Academic Institutions*
  - Ashley J. Stevens
  - World Intellectual Property Organization (WIPO), Geneva, Switzerland, March 2016,
  - available at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=332588

Questions?

Tea / Coffee

Session 7
Selected Case Studies
Q&A