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# How to start a biotechnology company

February 2, 2006

UCLA



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# Why start a biotechnology company?

- Technological innovation can create competitive advantage (when properly protected).
- What can we do better, smarter, faster, cheaper?
- In the early days of biotechnology, the potential was thought to be in drug development
  - That protein-drugs would have
    - lower toxicity
    - superior bioavailability
    - high efficacy
- Technology Push or Market Pull?

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## A brief history of biotechnology

- Recombinant DNA methodologies first invented in late 70' s and continually refined
- Courts rule that DNA is patentable
- Scalable
- Flexible
- Enabling
- What should we make?

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## What is a biotechnology company?

- Generally refers to any company using recombinant DNA technology

AND (especially on Wall Street)...

- Any small, start-up company pursuing drug discovery

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## What elements are required?

- Market Niche or Need
- Entrepreneur
- Technology
- Capital

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## Market niche or need

- Most biotechnology companies focus on pharmaceutical discovery
- Why?
  - Low volume, high value
  - Relatively low plant, property and equipment requirements
- Other applications include agriculture, industrial

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## What is an entrepreneur?

- Risk takers
- Pursue opportunity without regard to the resources they currently control
- Have a vision of success
- View change as an opportunity
- View themselves as agents of change
- Can thrive in the right environment

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# Technology

- Licensing technology
  - Bayh-Dole Act
- Protecting technology
  - Private versus public ownership
- Developing technology



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## Challenges to Technology Commercialization

- Recognition of potential
- Avoiding technology push?
- Focusing on market pull?
- Regulatory hurdles
- Access to capital
- Management

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## Technological innovation is not always obvious!

"This 'telephone' has too many shortcomings to be seriously considered as a means of communication. The device is inherently of no value to us."

*Western Union internal memo, 1876.*

Other examples include:

- Steam engines
- Computers
- Internet
- Recombinant DNA

## What is Technology Push?

- An innovator sees an opportunity to profit from a technology that has little or no current market. An "entirely new" market is created, based on the novel capacities of the technology.
- Users do not know they need a product until it is there.

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## Examples of Technology Push

- Xerox machines
  - Polaroid cameras
  - Transistors
  - Fax machines
  - Integrated electronic circuits
  - Beta-max
  - Laser discs
  - FlavorSaver
  - DVDix
  - TPA?
  - Camera phones?
  - iPods?
  - Biotechnology?
  - GMOs?
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## What is Market Pull?

- Occurs when existing firms seek better technologies to reduce their costs of production or to make marginal improvements in the quality of their existing products.
- The market "pulls" technology into it. A need exists, and there is currently no technology to meet the need.

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## Examples of Market Pull

- VHS format
- GUI interfaces
- CD ROM
- Google?
- Apple's music store?
- Biotechnology?
- GMOs?

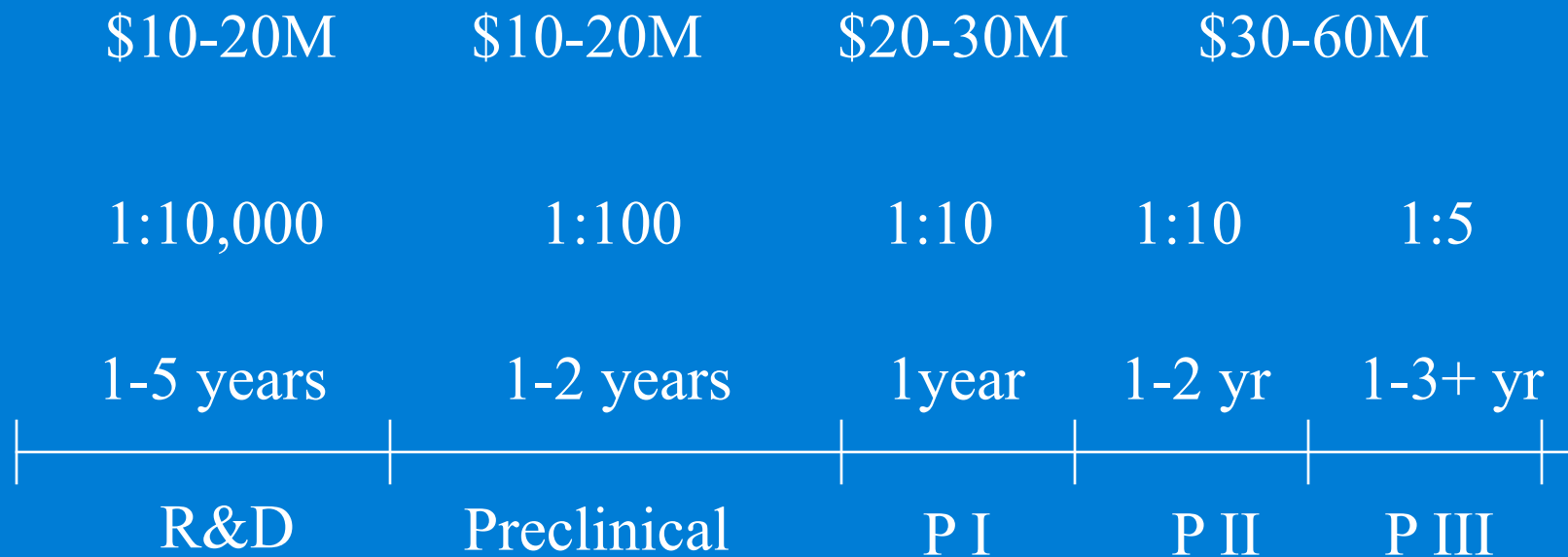
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# Pharmaceutical product development

- R&D
  - Screening
  - *In vitro* characterization
  - *In vivo* pharmacology, ADME (Absorption, Distribution, Metabolism, Excretion)
  - Preliminary toxicology
- Preclinical
  - Process chemistry (GMP)
  - Toxicology (GLP)
  - Clinical plan
  - File IND (Investigative New Drug)
- Clinical
  - Phase I, Phase II
  - Phase III
  - NDA (New Drug Application)

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# Product development timeline





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## Sources of Capital

- Revenue
- Banks
- SBIR' s
- Angels
- Venture Capital
- The three F' s

# What is Venture Capital?

- Unsecured equity investing
- Money is invested in return for stock
- Investment returns are generated when that stock can be sold at a significantly higher price.

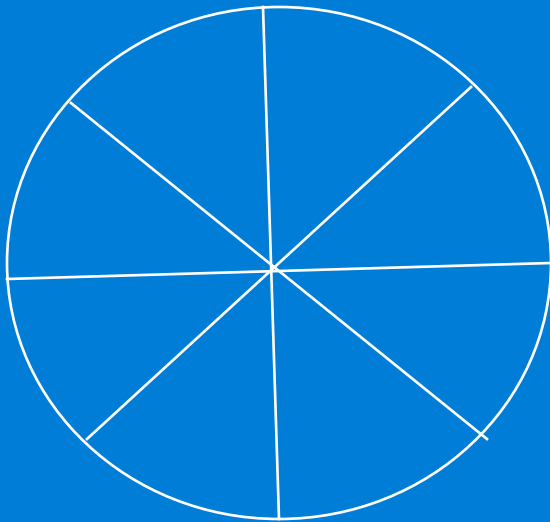
# Venture Capital

- Venture capitalists generally:
  - Finance new and rapidly growing companies;
  - Purchase equity securities;
  - Assist in the development of new products or services;
  - Add value to the company through active participation;
  - Take higher risks with the expectation of higher rewards;
  - Have a long-term orientation BUT are generally structured as 10 year limited partnerships
  - DOES THIS FIT BIOTECH PRODUCT DEVELOPMENT TIMELINES?

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# What is market capitalization?

The total number of shares issued by a company  
X  
the price per share  
=  
the market capitalization or value of a company



$$8 \text{ shares} \times \$2/\text{share} = \$16$$

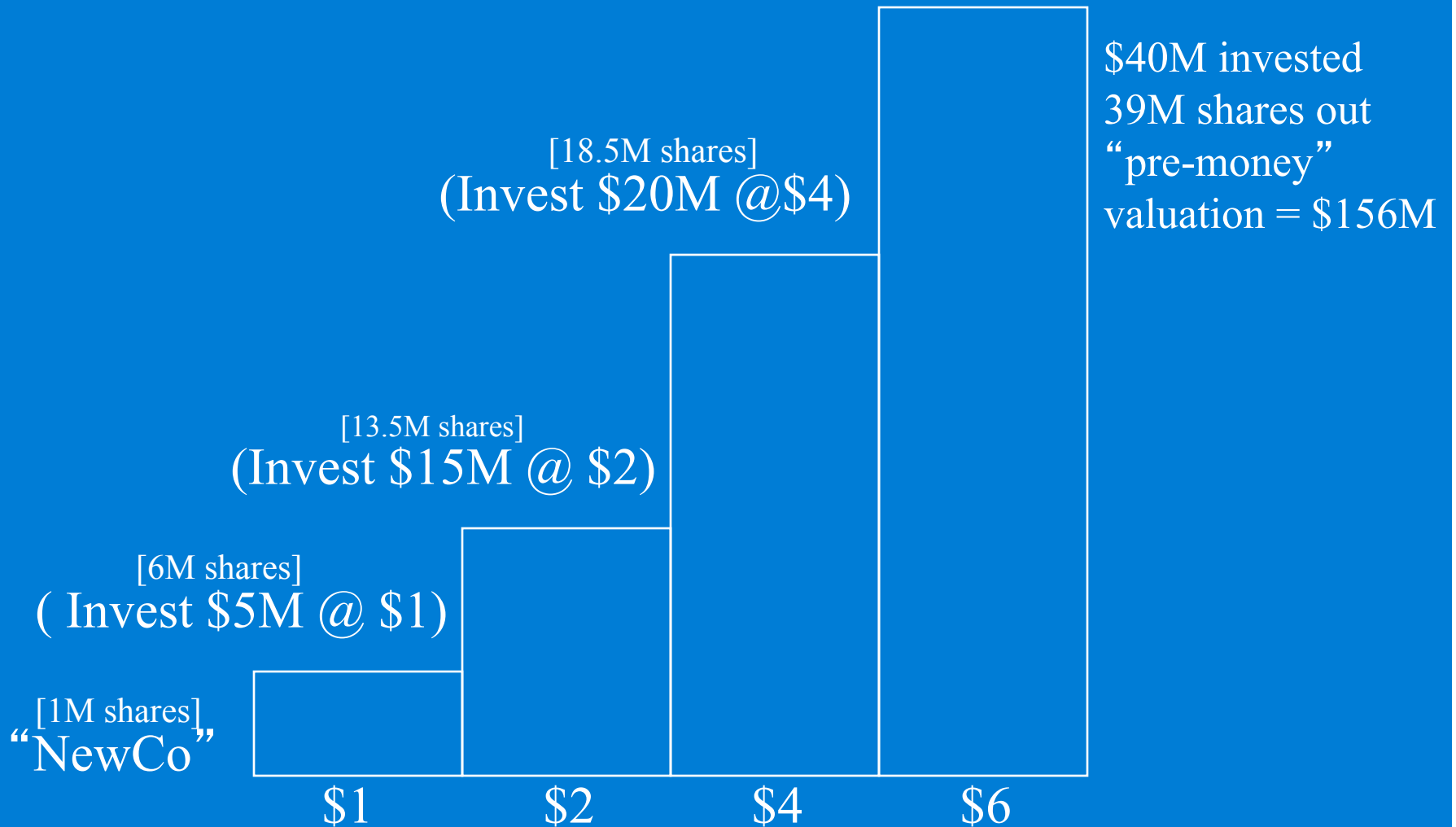
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## The financing lifecycle of a biotech co.

- Seed
- Start-up or “First” round
- Second round
- Mezzanine round
- IPO
- Secondary offering

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# Valuations increase with investment



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## Valuing companies

- Traditional investors use financial parameters to value companies. These include:
  - Multiples of revenues
  - Multiples of earnings or “PE ratios”
- But biotechnology companies do not have revenues or earnings for 10 years or more! How are they valued?

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## Seed stage (<\$1M)

- Write business plan
  - Management, market, technology, products
- License technology
- Attract angel investors or specialized firms
- The 3 F' s



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## Start-up or “First” round (\$1-10M)

- Bring in professional investors
  - How is the company valued?
- Attract management team
- Build-out facility
- Begin product development

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## Second Round (\$10-30M)

- Typically still VC investors
- Continue product development
- Provide “proof of principle” or other “validation”?
- What justifies a step-up in valuation?

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## Mezzanine round (\$25-50M)

- VC and “later stage” investors
- Continue product development
- Provide “proof of principle” or other “validation”?
- What justifies a step-up in valuation?
- In clinical trials?

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## **IPO round (\$100M)**

- Mutual funds and institutional investors
- Complete clinical trials?
- Conduct product development on additional candidates?
- How much risk are these investors being asked to take?

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## What is a FIPCO?

Fully Integrated Pharmaceutical Company

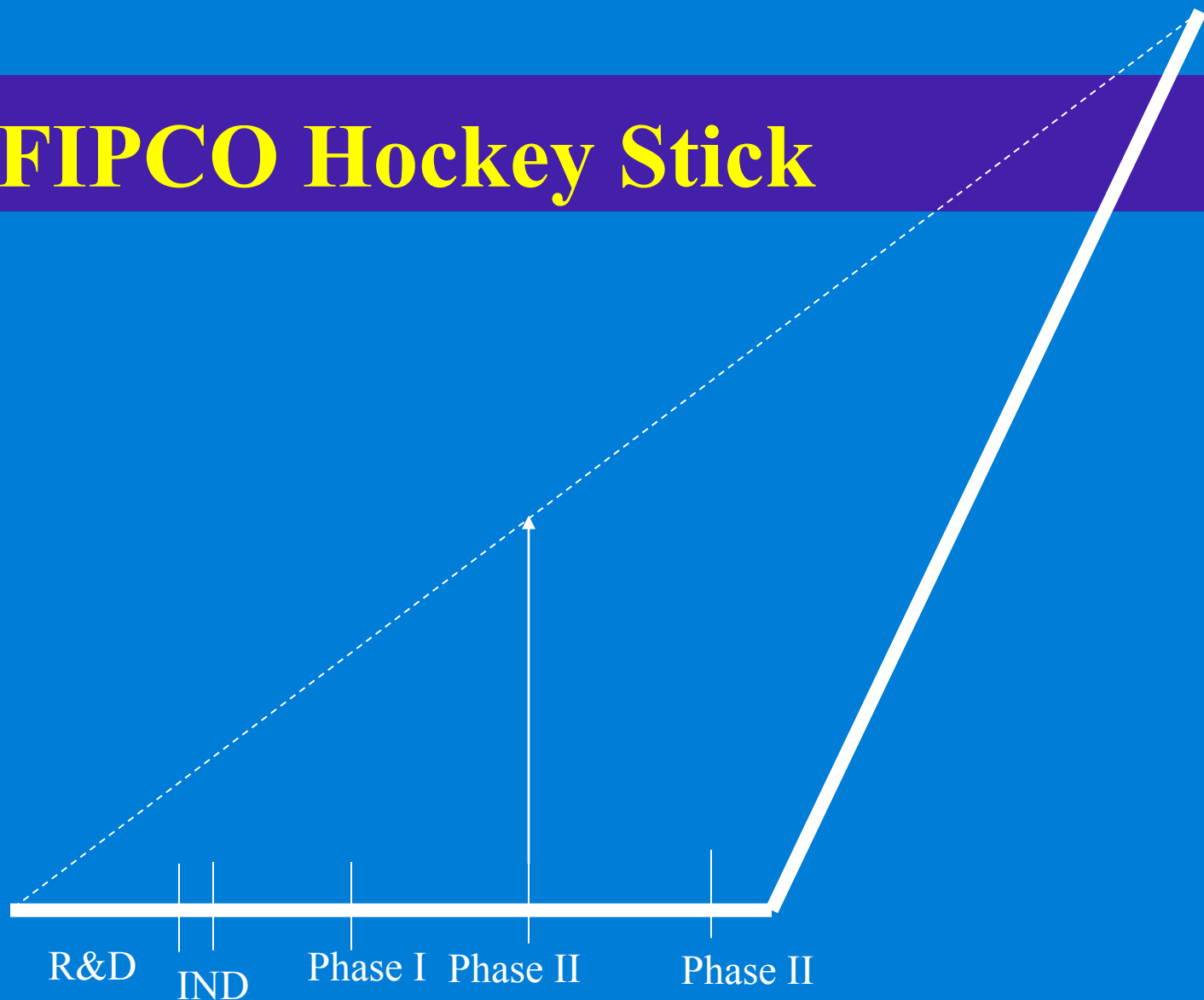
Examples: Amgen, Genentech, Chiron, Biogen, Gilead,  
MedImmune

Focus on proprietary drug discovery

High Risk  
High Return

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# The FIPCO Hockey Stick



The NPV of failure in a single-product company is \$0

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## The Fundamental Flaw

- The traditional FIPCO business model requires too much cash from investors upfront and loads a disproportionate risk on later stage investors.

# A Few Words on Biotech Business Models

## 1. FIPCO

Examples: Amgen  
Genentech, Chiron,  
Biogen

Focus on proprietary,  
self-funded drug discovery

High Risk  
High Return

## 2. Platform

Examples: HGS, Exelixis,  
Millennium, Ceres

Sell platform to multiple  
customers while pursuing  
forward integration

Low Risk  
High Return

## 3. Service

Examples: Incyte, Aurora,  
Gene Logic, Lion

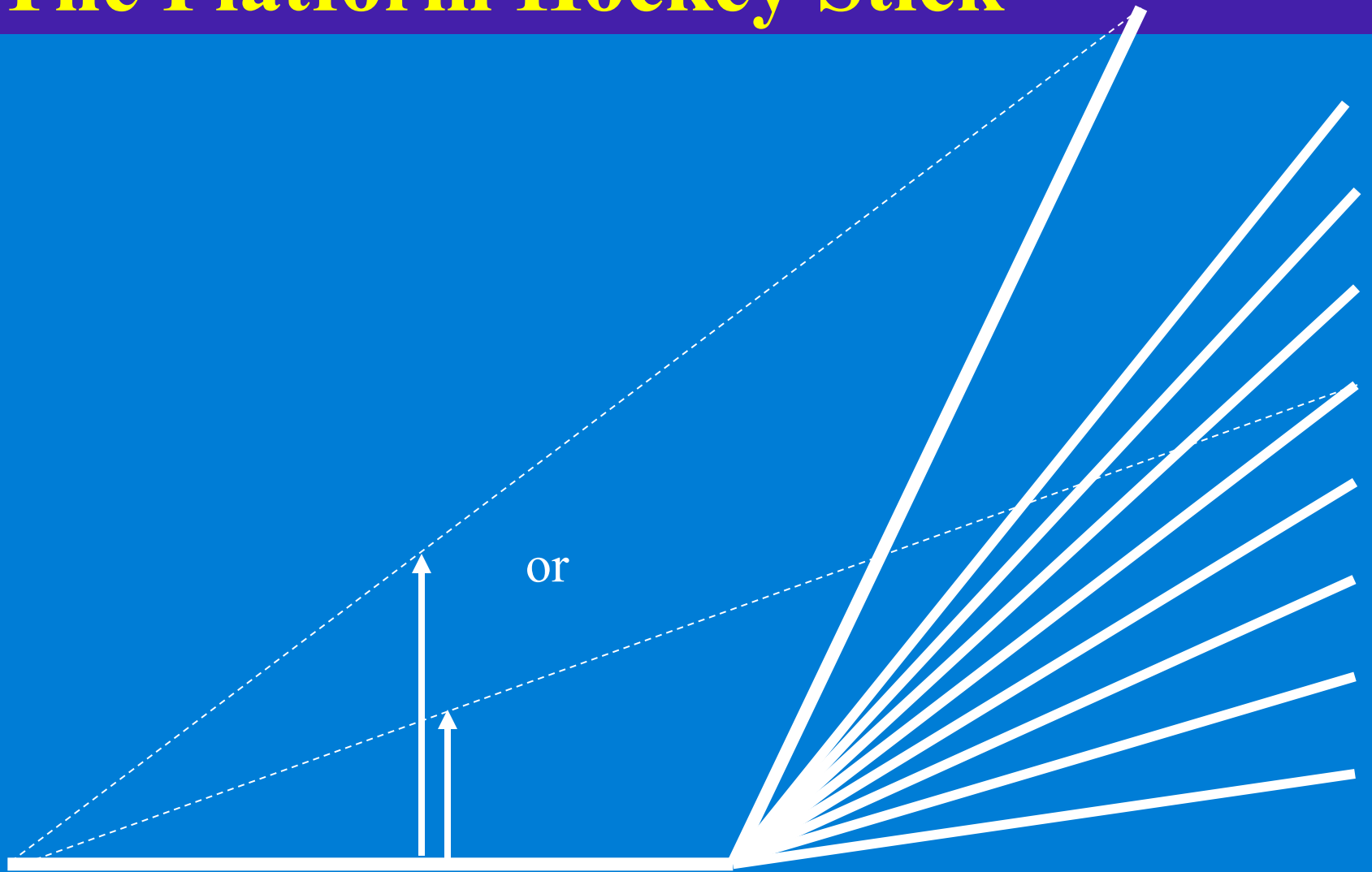
Focus on providing high-  
value services to pharma

Low Risk  
Low Return



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# The Platform Hockey Stick



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## What makes biotech so expensive?

- Long product development cycles
- Regulatory hurdles
- Technology development
  
- Are there alternative products/industries for which biotechnology is applicable?
- Will there be start-up companies in these areas?

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## How to start a biotechnology company?

- Do everything all entrepreneurs have to do
- AND
- Manage product development risk while;
  - Attracting capital at attractive prices