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Lets Get It Started!

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Summer Program on Bioentrepreneurship 2009

- Let's Get It Started! (today)
- Crown Jewels and War Chests: All About IP (July 21)
- It's Not All Medicine: CleanTech Meets BioTech (August 25)



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Lets Get It Started!

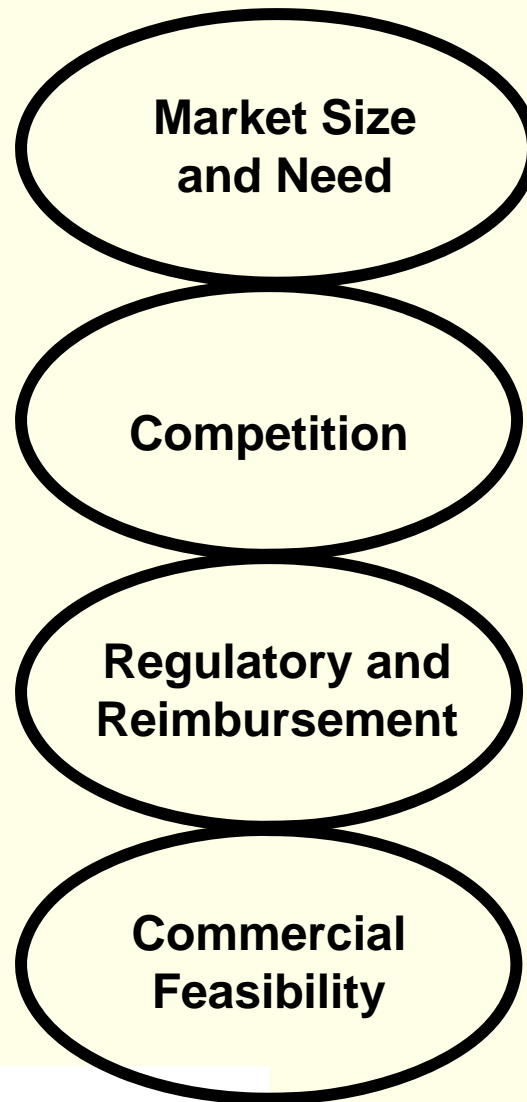
- Evaluating An Opportunity
- Team Building
- Equity Basics



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Evaluating an Opportunity



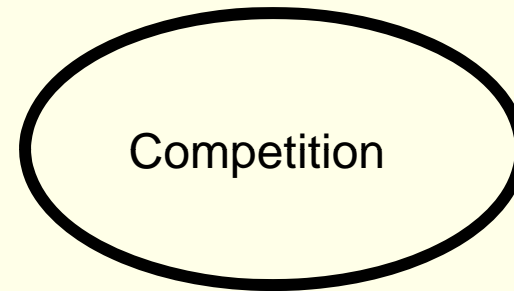
When Is an Idea Good Enough?

- What problem are you solving?
- Who will use it and why?
 - Fewer side effects
 - Shorter recovery
 - More convenient dosing
 - Works when alternatives won't
- How big is the market?
 - Incidence and prevalence of condition
 - Number of procedures
 - Number of potential customers
- Is the market growing or shrinking? How fast?



Understanding the Current Landscape

- Who currently serves the market
 - How much do they sell?
 - How will they react?
- What other applicable technologies are in development?



Understanding the Current Landscape

- Regulatory approval path
 - Acute vs. Chronic
 - Trial size
 - Trial duration
 - CMC
 - Toxicology
- Safety, safety, safety!
- Reimbursement
 - Who pays for current therapies and how?
 - Data requirements for reimbursement approval
- Beware of changing landscape!

Regulatory and Reimbursement



Anticipate Commercialization Strategy

- Direct sales vs. partnership
 - Specialty sales vs. partnership
 - Number of target customers
 - Anticipated selling prices
- Reality Check Thought Process
 - What do other companies do
- Don't need all the answers, but can guide team-building

**Commercial
Feasibility**

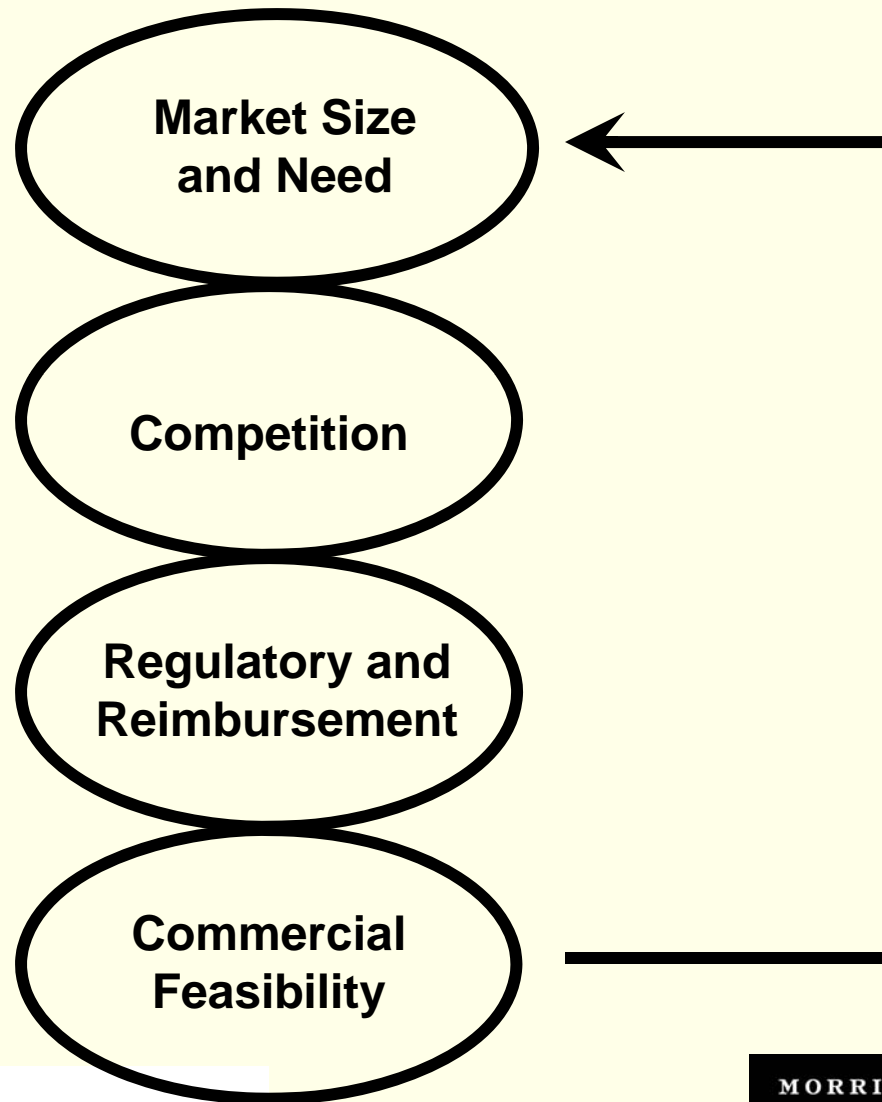


Where Can I Find Information?

- Company SEC filings (www.sec.gov)
- Securities analyst reports
- CDC
- NIH
- FDA
- Foundations and Advocacy Groups, e.g.,
 - AHA
 - ADA
 - Michael J. Fox Foundation
 - Cystic Fibrosis Foundation



Evaluating an Opportunity



What Team Do I Need?

- What will the primary activities of the new company be in the first 2 years?
 - Research and Development
 - Clinical trials
 - Reimbursement
 - In-licensing/out-licensing
 - Raising capital
 - Protecting IP
- Plan around value creating milestones
- Consultants and employees
- Board of directors
- Scientific or clinical advisory board

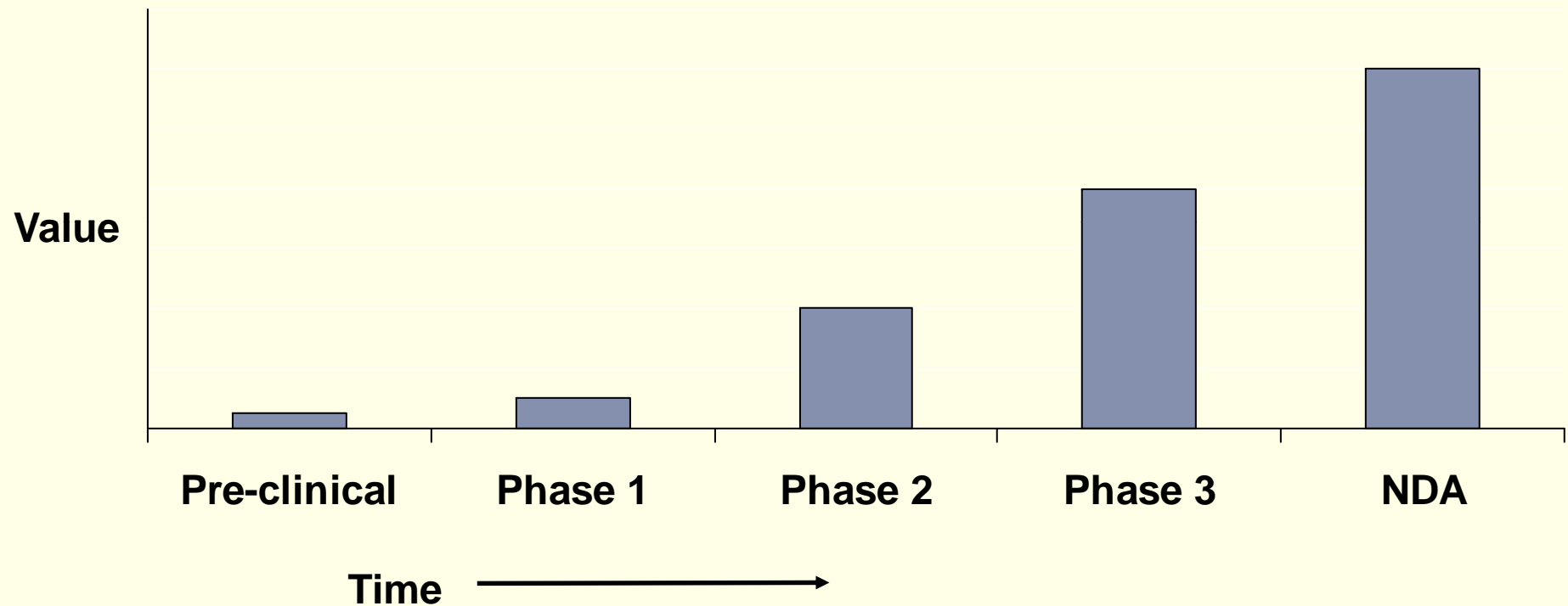


Getting It Together

- Creating a company
- Issuing founders' stock
- Protecting intellectual property
 - Building fences
 - Can others prevent me from getting to market? (FTO)



How Should I Think About Raising Capital?



Create a milestone-based budget around value inflection points



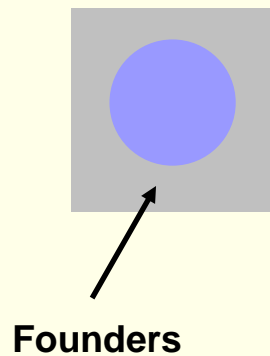
Value Inflection Points

- There are many potential value enhancing milestones
 - Animal data
 - CMC development
 - Toxicology
 - Formulation
 - Delivery technology
 - Key hires
 - Supply agreements
 - Development agreements
 - Patent filings
 - Patent issuance
 - Pre-IND meeting
 - Special protocol assessments
 - End of Phase 2 meetings
 - Etc.

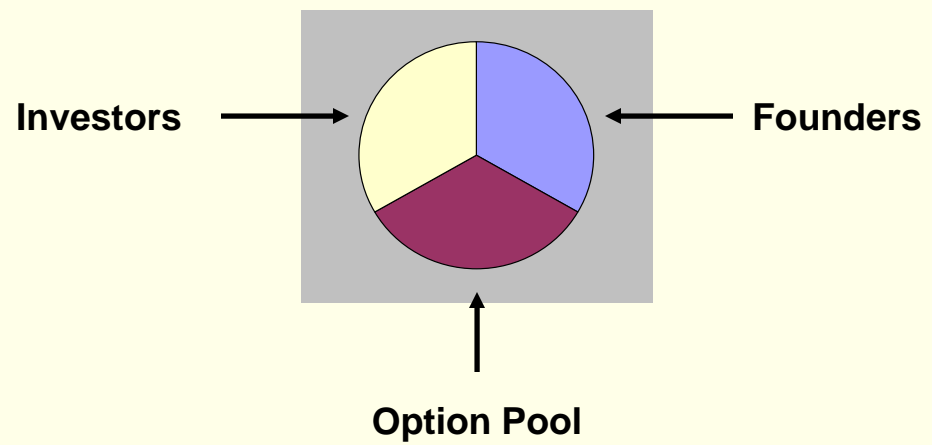


Cap Table Mechanics

Initial Capitalization

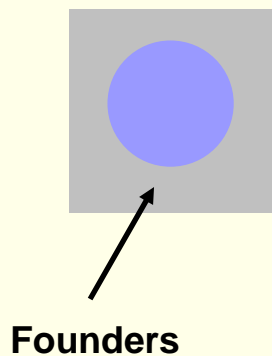


First Round Financing

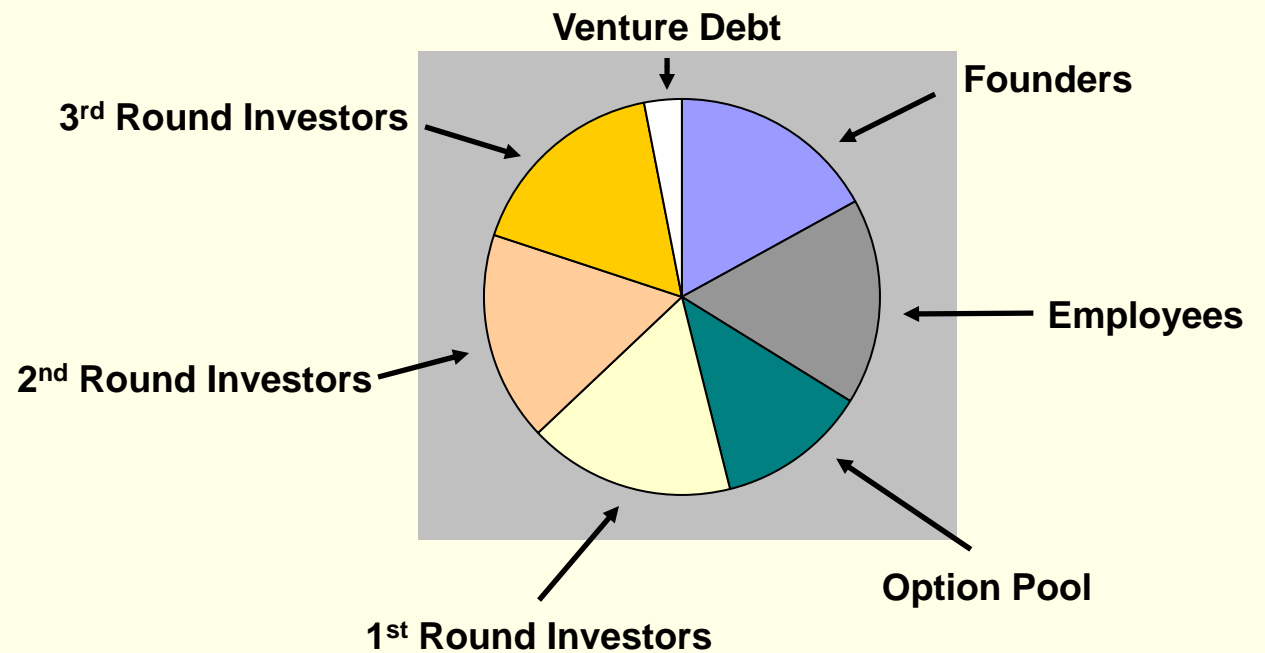


Cap Table Mechanics

Initial Capitalization



Later Capitalization



Founders' Stock Allocations

- Initial contributions
- Anticipated contributions
- Role within organization
- Part-time v. full-time
- Experience
- Special expertise
- Etc.



Reality of Ownership

- Greatest % ownership on formation
- No magic formula for founders' allocations
- Dilution offset by increased value
 - People
 - Capital
 - Others (technology, etc.)



Just Do It!

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