Let's 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)
Lets Get It Started!

- Evaluating An Opportunity
- Team Building
- Equity Basics
Evaluating an Opportunity

- Market Size and Need
- Competition
- Regulatory and Reimbursement
- Commercial Feasibility
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!**
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
Where Can I Find Information?

- Company SEC filings ([www.sec.gov](http://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

- Market Size and Need
- Competition
- Regulatory and Reimbursement
- Commercial Feasibility
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)
Create a milestone-based budget around value inflection points
Value Inflection Points

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

Initial Capitalization

First Round Financing

Investors

Option Pool

Founders
Cap Table Mechanics

Initial Capitalization

Later Capitalization

- Founders
- 3rd Round Investors
- 2nd Round Investors
- 1st Round Investors
- Employees
- Option Pool
- Venture Debt
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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