

Welcome!

Entrepreneurship in Life Science: A
Thrill a Minute

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WHAT EVERY ENTREPRENEUR NEEDS TO KNOW WHEN STARTING A NEW BIOTECH COMPANY

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I. Understanding the Whole Discovery/Development Process

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Human Therapies

Target ID	Target Validation	Lead ID	Lead Validation	Preclinical (animal)	Clinical Trials (human) I Safety II Safety & efficacy III Efficacy	Regulatory FDA	Commercialize
400 targets identified, could be > 5000 <i>Risks:</i> <i>Wrong target</i> <i>Multiple pathways</i>	No rational method to success - animal models - can be expensive	Too many possibilities Often, pick the wrong ones	Is it druggable? ↓ What is the distribution in body? ADME*	model ≠ human Toxicology Toxicity	-\$ II- \$ x10 III- \$ x100 <i>Risks:</i> <i>Trial failure</i> <i>Dosing</i> <i>Toxicity</i>	FDA and biotech companies are naive FDA is inconsistent	\$ Competition MDs don't like change Side Effects

Discovery

Random v. Rational Drug Design

Development

Sell

ADME-for drugs. Look at the cellular level

A Absorption – is it soluble? Give orally? Parenterally?
D Distribution – to organs/cells
M Metabolism – what happens to the drug and byproducts
E Excretion – how, when (e.g., half life in the body)

Human Therapies

HUMAN THERAPEUTICS

What's Hot:

Platform/Tool Cos. v.
Products

Symptoms v. cure
Disease Pathway

Assays
Side Effects
Receptors
Drug Delivery

INVESTMENT CRITERIA

CEO

Is it R or D?

Intellectual Property-

- Freedom to operate
- Patent portfolio

How will the \$ be used?

What is the Technology?

Is it a Breakthrough?

EXITS

Exits

IPO – is window open?

Purchase (Large
Pharma/Large Biotech)



II. The Technology

- A. IP must be Adequate and Sufficient
- B. Definition of Value Added must be Clear and Obvious
- C. Application of Technology must be Straightforward



III. The Money

- A. Think about the Amount of Time the \$\$ will Buy
- B. What Value adding Milestones will be Met & When
- C. When will you need more Money
- D. Don't Worry about Valuation or Protecting Your Ownership Position

IV. The Business Model

- A. Medical "Need" is Not Enough
- B. Don't Assume or Expect that Everything Other than the Science is Obvious...It Isn't!
- C. Remember Willie Sutton
- D. Animals do not = Humans
- E. E. Focus
- F. Companies often don't end up being what they thought they were going to be in the beginning



V. The CEO

A. Need Sooner Rather than Later

B. Go for the Best

C. Don't Try to do this Yourself. You Wouldn't let the CEO do the Research!

VI. The Business Presentation

- A. What Do You Do
- B. What Problem Do You Solve
- C. What is Your Unfair Advantage
- D. Describe Your Patent Estate
 - i Can you block Others from Operating in this Space
 - ii Do You have Freedom to Operate
- E. How Long will this Money Last
- F. How Good is your CEO
- G. How are you Going to Spend My Money to Add Value to My Investment and Allow You to Raise More Money at a Higher Valuation Before My Money Runs Out