The Business of Science
Filling the Gap

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To succeed in business, you need to be...

- Driven by profits
- Aware of the needs/characteristics of the market
- Focused on products, not interesting science
- Collaborative internally
- Competitive externally

What you learn as an academic

- Knowledge is an end in itself
- Don't reveal all that you know
  - In grant applications or publications
- Today's collaborator can be tomorrow's competitor
- The less you depend on other people the faster your research will go

Business Survival Skills

- Understanding the difference between pure science and drug development
- Appreciating how market forces affect development strategies
- Understanding the difference between investors (or shareholders) and the NIH

Survey Methodology

- Informal phone survey of big and small pharma/biotech
- Anecdotal evidence

The training that Post-Docs need (consensus)

- Overview of drug development process
- Business basics (profit requirements)
- Team skills
- Conflict resolution
- And later, management skills, negotiation skills, project management, budgeting

The training that Post-Docs get
(if any)

- Company history
- Benefits
- Sexual harassment
- IP requirements
- Health and safety
- Use of animals

The Consequences

“ Scientists want to pursue science for knowledge sake... Not advancing our commercial objectives... Fall in love with research program... Unaware of experimental critical path... Results don’t affect our commercial path... Wasted time from non-communication... No team orientation; not communicating things that rest of team should know... Not calling for help... People in leadership positions without skills or training.”

Mind the Gap

Why don’t post-docs get an orientation into the business?

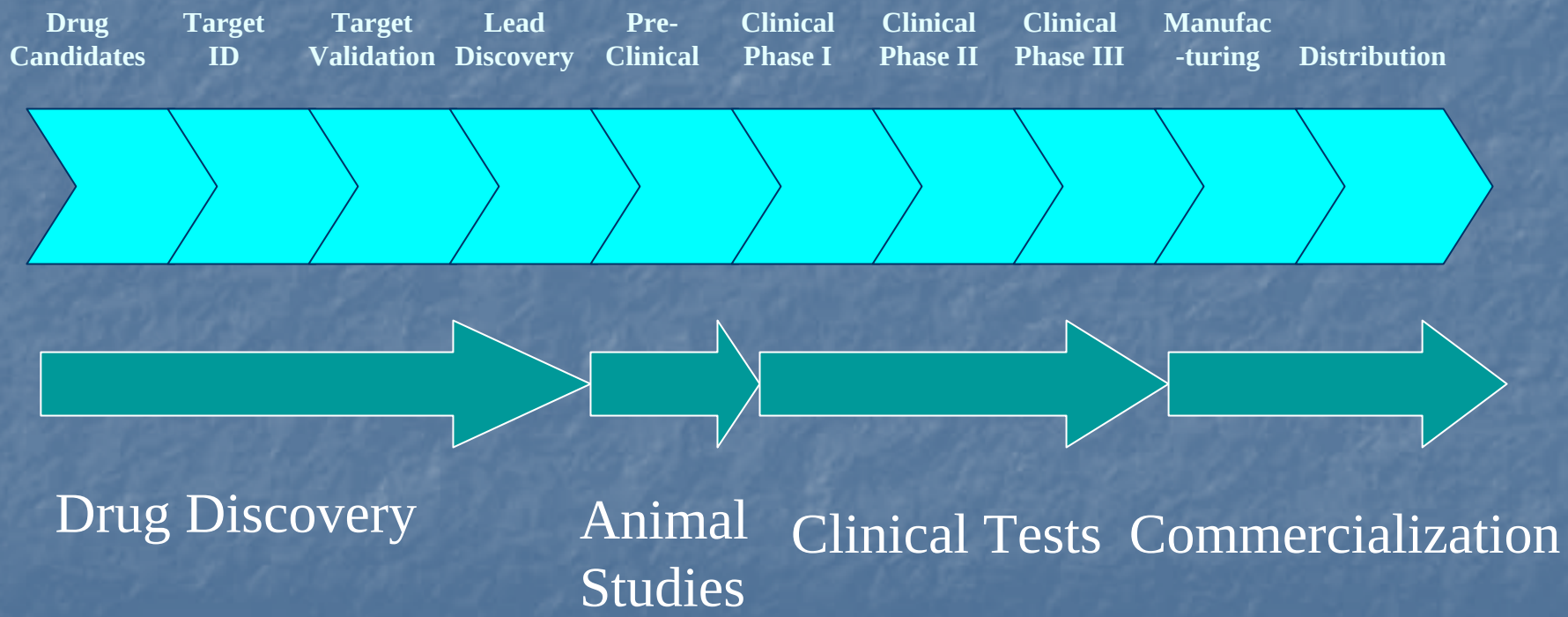
- Need to establish R&D credentials quickly
- The ‘protective’ VP, R&D
- Focus on regulated areas: harassment, IP
- The Mushroom Theory of Management

New Post-Doc Orientation

A proposed syllabus

- Differences between science and drug development
- Drug development overview: process, costs, business issues, risks and mitigations
- Why and how our business is regulated
- Our company strategy
- How we compete

The Drug Development Process



Business Strategies Affect Target Selection

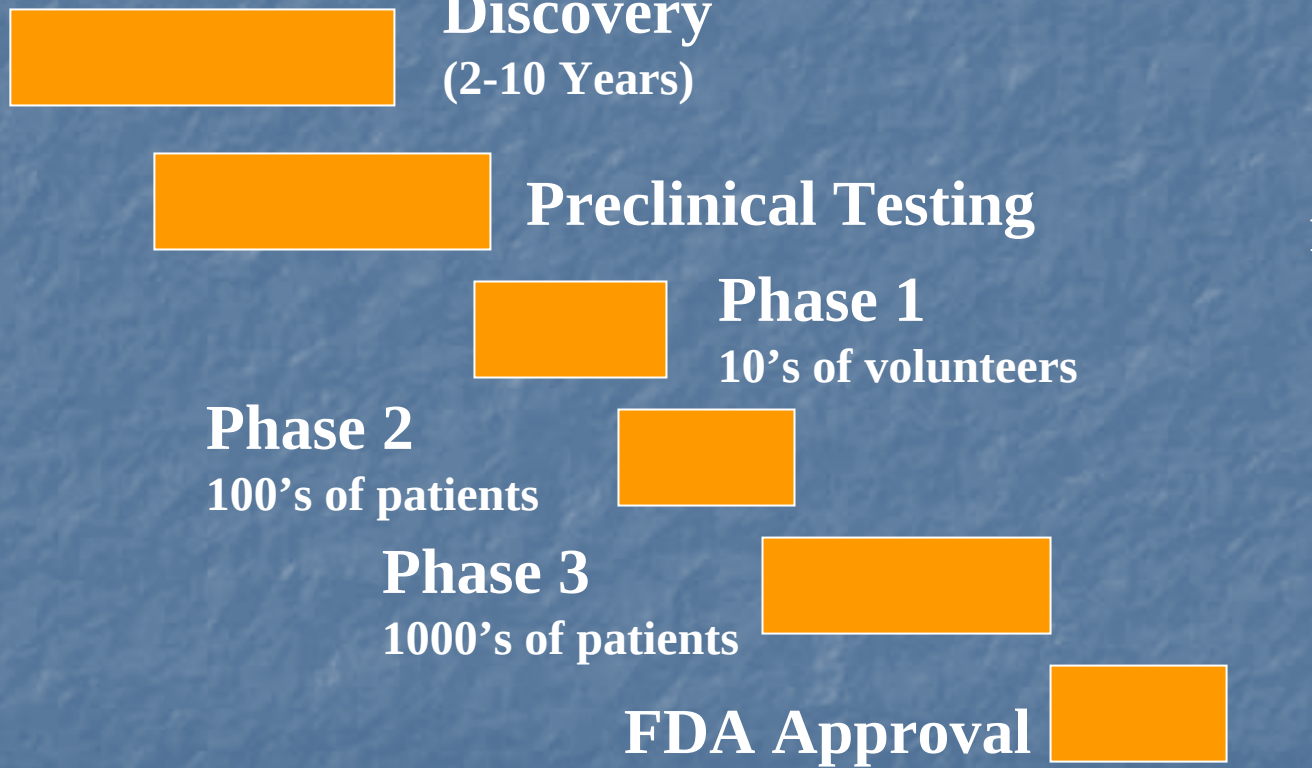
- Concentrate on disease (cancer, obesity, cardiac)
- Concentrate on tissue (lung, breast, brain)
- Concentrate on therapies (RNAi, kinases)

- How big is the market?
- What is the competition?
- What experience do we have?
- Is there synergy with our other products?

Drug Development: The Business Issues

- Does the putative therapy fit with our business strategy?
- Exactly what disease(s) will the therapy be directed to?
- How will the drug be delivered?
- Do we have in-house experience with the technology?
- Will the therapy be better than existing treatments?
- Do we have the expertise to manufacture the drug?
- Do we have the expertise to market the drug?
- What are the expected profits? How much can we charge?
- What are the risks and how can they be mitigated?

Compound Success Rates and Timing by Stage



Success Rates

5,000 –10,000 Screened

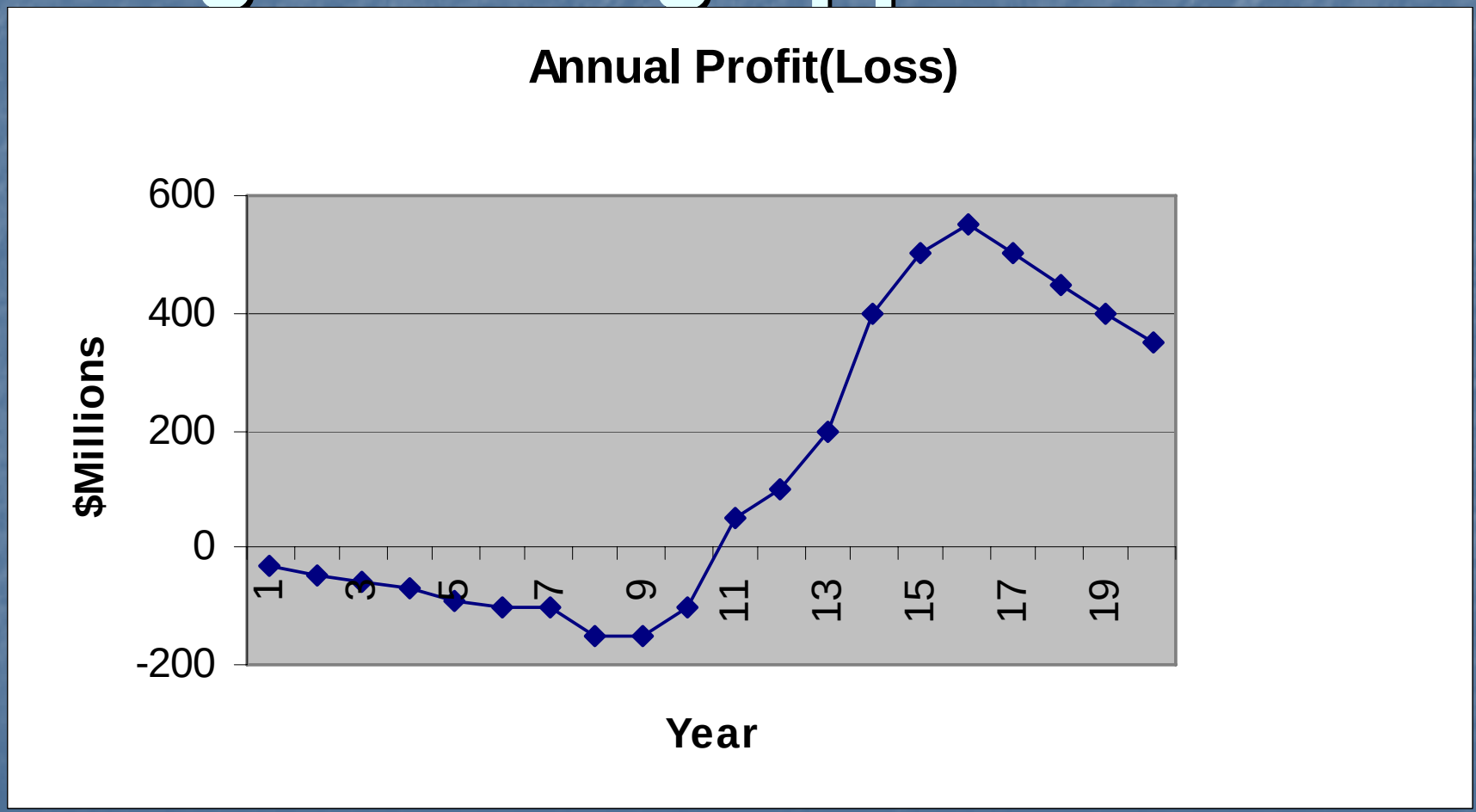
250 enter Preclinical testing

5 enter clinical testing

1 approved

Source: Phrma.org

How much does it cost to get a drug approved?



Why don't all targets generate therapies?

- Just doesn't work (of mice and men)
- Similar symptoms from different causes
- The cure is worse than the disease
- ADME/tox: absorption, distribution, metabolism, excretion/toxicity
- Most diseases have complex causes
- Diseases have a time course
- Differences in individual's DNA causes them to metabolize drugs differently (pharmacogenomics)
- ...and so on

Mitigating the Financial Risks in Drug Development

- Killing unpromising candidates at the earliest opportunity
- Maintaining marketing exclusivity as long as possible
- Populating a product pipeline
- Spreading the risk

The Shape of the Pharma/Biotech Industry

- Successful companies need portfolio of products in different stages of development
- It is extremely difficult to build a new fully integrated biopharma company
- Risks of drug development need to be strategically managed (partnerships, joint ventures, out-licensing)
- Successful companies – big and small - need partners in all phases of the drug development lifecycle
- Companies are specializing in all phases of the value chain

New Post-Doc Orientation
A proposed syllabus

- Team-building; knowledge-sharing; collaboration
- Communication/presentation skills
- Conflict resolution
- Sources of information