



# Cultural Disconnect – Academics vs Product Development

Obstacles to Translation Conference  
March 1-2, 2006

# Neosil, Inc.

- **Biotechnology/dermatology company**
- **November 2005**
- **MPM Capital and Burrill & Co.**
- **Developing mid-stage products**
  - **Broad-spectrum antimicrobial**
  - **Peptide hair growth product**
  - **Others in progress**

# Navigating Academic-Industry Speed Bumps

- **Five (?) decades of academic tradition and bureaucracy**
- **Intellectual property**
- **Financing**
- **Timely decision-making**
- **Conflict of interest**

**Personal journey in two worlds: academic dermatologic investigator 25 yr [co-founder of Connetics]; academic administration; consultant; Neosil**

**Experiential, necessarily biased. Also, reflective of start-up to early stage public company experience, not necessarily big pharma.**

# Tradition and Bureaucracy

- **Disconnect:**

- Discovery vs application
- Rewards and risks in a circumscribed world vs public stock holder (or investor) demands for progress and accountability
- Deliberate vs expedite

- **Decades (centuries) of academic culture that equated / equates commerce with impurity (e.g., Washington University-Monsanto agreement)**

- **Exceptions create new norm of academic-industry fluidity**

- Genentech (Botstein, Snyderman, Scheller)
- Chiron (Scharschmidt)
- Judith Swain (Stanford, UCSD)
- “The dark side...”

# Intellectual Property

- **Enormous impact of Bayh-Dole legislation on universities**
- **Faculty level: discovering something of potential value → fundamental conflict →**

**Free dissemination of information vs capturing IP of potential value for proprietary exploitation**

- **Two extremes in IP approach – Stanford University (OTL) and “D” University**
- **Two extremes in valuing (financially) the work of faculty – Stanford (1/3...) and “S-I” Institute**

# Financing

- **Nurturing the idea – Role of individual, department, school, university; sets up potential conflict of interests**
- **Development pathways – Internal vs external incubators, licensing only, producing real value (proof-of-concept)**
  - Connetics lesson – strong lab data interesting for mechanistic insights; clinical data attracts venture investors
- **Finding investors – the long term kind**
  - What investors expect of you vs what they fear from you – time, decisions, flexibility, use of money, risk mitigation (e.g., redundancy, complementarity)

# Timely Decision-Making

- **Deliberate vs decide**
- **Perfect is the enemy of good-enough**
- **Time is money**
- **Mitigating likelihood of failure – Connetics lesson**
- **Execute, execute, execute...**
  - Team approaches to product development, including exhaustive planning (prevent time loss at each step), GMP production, formulation, preclinical (PK, tox, etc.)
  - Team approaches to clinical development

# Conflict of Interest

- **The key to bridging the worlds of Academics and Drug Development**
- **Two extremes for consulting**
  - Stanford University (20%) vs “P” University (0%)
- **C-o-I: evolution-in-progress**
  - Trusted judgement
  - Guilty until proven innocent → VIDEO

# Conflict of Interest

## Question:

- **Does the current atmosphere surrounding the conflict-of-interest discussions impede innovation or even stifle research?**
- **Hypothesis: Yes, particularly in orphan diseases**
  - **Discoverer-investigators may themselves be magnets to attract patients with rare disorders from around the world**
  - **Barring them from participating in, or even leading, an early stage clinical trial is wholly inappropriate**
  - **Represents the triumph of form over substance**
  - **Monitoring wholly appropriate**