Making Natural Product Research Work: The Importance of Collaborations and IP

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Universities – the incubator for the biopharma industry

- In 2006, US universities launched more than 550 startups, most in biopharma (2/3 of biotech startups from academia)
- Vast majority of biologics on market today developed with university input
- Top 20 biotech patenting entities dominated by universities; all of “most cited” biotech patents are from academia
Universities increasingly are primary engine of discovery / innovation for bio

- Company pipelines drying up - since 1980, large biopharma companies’ share of new FDA-approved drugs has declined from ~75% to ~35%
- >40% of pharma execs want to partner with academia or acquire biotechs to acquire innovation pipeline – new models
- As biopharma and VC move downstream, academia must address the risk and uncertainty of translation
Lifecycle of a Product: Clinical Development

10,000 compounds in the beginning

1,000 compounds *in vitro* testing

10 compounds in the clinic

1 new Medicine

Preclinical Research

Clinical Phase I

Clinical Phase II

Clinical Phase III

Registration

~14 years
Lifecycle of a Product: Clinical Development

R&D costs in 2005

R&D spendings ($B)

- Preclinical: 10.3, 26%
- Phase I: 2.3, 8%
- Phase II: 4.7, 12%
- Phase III: 10.2, 26%
- Approval: 2.8, 7%
- Phase IV: 5.3, 13%
- Uncategorized: 4.4, 10%
- Total: 39.9

Clinical development
Key opportunities – and challenges – with natural products

- Historical success
- Natural products libraries offer diversity of leads not typically found in synthetic chemical libraries; BUT...
- Longer discovery timelines
- Complexities in sourcing and in large scale production
- Other challenges in patenting/regulatory schemes
- Uncertain disclosure requirements heighten risk
University collaborations critical in biopharma – especially natural products

- Screening/drug development capabilities previously only in industry; today in academia
- Funding agencies / foundations emphasizing translation; new NIH entity and programs
- New models of collaborations and partnerships (companies, NFPs, others)
- Universities engaging aggressively in entrepreneurial / economic development activities
- Universities well-positioned as “honest broker” in the natural products space
- Academic culture change – best talent wants to collaborate with industry – and change society
Role of IP in innovation “ecosystem” between academia and industry

- US Law (Bayh-Dole Act) and similar laws elsewhere gave universities title to patents
- Goal - societal and economic benefit
- National policy frameworks allow universities to grant licenses, including exclusive licenses
- Bayh-Dole provides flexibility for universities in financial terms of licensing
- Patents (and Data Exclusivity) – provide essential exclusivity needed to attract investors
Critical components for universities within innovation ecosystem

- Strong, certain, predictable IP system in which university can be strong player/partner – high-risk of biotech requires robust IP system
- Strong science (where it all starts)
- Capital
- Talent
  - Founders / Employees
  - Investors / Advisors
- Industry partners/collaborators
Thank you for your attention

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