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

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Universities – the incubator for the biopharma industry

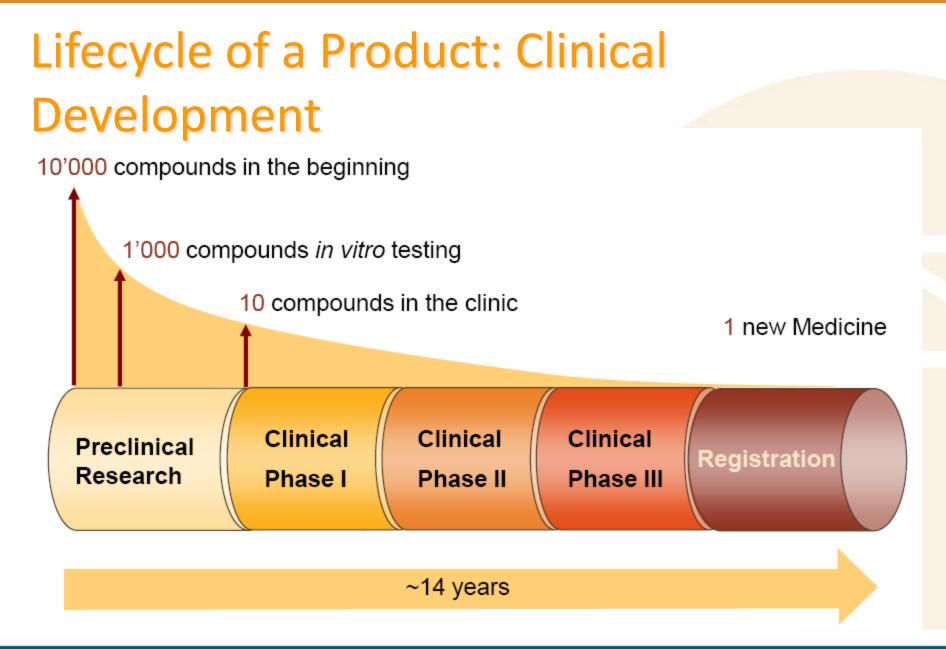
- In 2006, US universities launched more than 550 startups, most in biopharma (2/3 of biotech startups from academia)
- Vast majority of biologics on market today developed with university input
- Top 20 biotech patenting entities dominated by universities; all of "most cited" biotech patents are from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



Universities increasingly are primary engine of discovery / innovation for bio

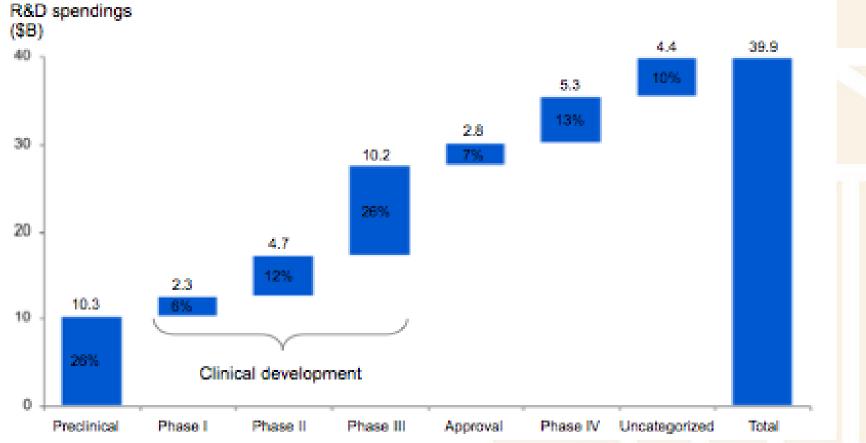
- Company pipelines drying up since 1980, large biopharma companies' share of new FDAapproved drugs has declined from ~75% to ~35%
- >40% of pharma execs want to partner with academia or acquire biotechs to acquire innovation pipeline – new models
- As biopharma and VC move downstream, academia must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







Lifecycle of a Product: Clinical Development



R&D costs in 2005



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
- <u>Uncertain</u> disclosure requirements heighten <u>risk</u>





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 <u>exclusive</u> 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 – highrisk 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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