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After In-licensing and Towards an Exit

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IP Lifecycle of Biotech Startups

- Biotech startups "graduate" between two major Intellectual Property (IP) transactions –
  - In-licensing of IP from a research institution or a founder
  - Out-licensing this IP, as further developed, to a global BioPharma company

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In-Licensing: The Players

- The Licensor (Research Institution)
  - The legal owner of the IP
  - Process managed by Tech Transfer Office (TTO)
- The Licensee (Biotech Startup)
  - Represents an “applied” vs. “basic research” point of view
  - Limited financial means
  - Entrepreneur vs. Seed Investor
- The Inventor (scientist)
  - Represents the knowledge and know-how
  - Emotionally involved (“brain child”)
  - Founder? “highway patent”?

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In-Licensing: TTO's Interests

- TTO's success is measured by –
  - Number of the institution's IP out-licensed
    - Increases probability of future revenues
    - Reduces internal IP expenses
  - Revenues
    - Preferably long-term royalty stream on product sales
    - Important for institution development & prestige
- TTO interest is to out-license to the most capable industry partners on the best possible terms

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In-Licensing: Startup's Interests

- Startup's in-licensing success is measured by –
  - In-licensing the required IP
  - Obtaining exclusivity
  - Reasonable milestones and royalty terms

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In-Licensing: Inventor's Interests

- Prestige & Recognition –
  - Commercial development; from lab to market
  - Scientific publications and collaborations
  - Benefit to mankind; personal legacy
- Income –
  - Commercial resources for research
  - Personal income from royalties and consulting

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Main In-Licensing Pointers

- Team-up with a veteran lawyer
- Negotiate the in-licensing with the requirements of the sub-licensee in mind
- Avoid risky development and commercial milestones (assume the worst case scenario)
- Delay all major payments to better times (assume the worst case scenario)

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Other In-Licensing Pointers

- IP quality
  - Expiration: How many years after time to market?
  - Freedom To Operate: Basic FTO analysis is highly recommended
  - Composition Of Matter and Use: Is COM strong? What uses (indications) are protected?
  - Know-how: Investigate know-how in “highway patents”
  - Ownership: Investigate patent waivers
- Exclusivity
  - Territory: Worldwide license is a must
  - Right to sublicense: A must
  - Right of sublicensee to further sublicense: highly recommended

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Other In-Licensing Pointers

- Startup's Diligence
  - Clinical/regulatory milestones: Assume worst case scenario
  - Resources: Assume worst case scenario
- Milestone Fees: Target late regulatory milestones
- Royalties on sales
  - Remember "royalty stacking"
  - Build royalty rates: e.g., up to $XM 3%, above $YM 4%
  - Minimal royalties: If needed - Assume worst case scenario and keep the right to terminate
  - Differentiate between territories with and without valid claims

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Between In & Out Licensing

- BioTech startups build value by lowering the perceived risks of product development and marketing
  - Main perceived risks: efficacy in humans, toxicity in humans, competition in market
  - Perceived IP risks can also be lowered -
    - Constructing a stronger IP portfolio by covering specific target indications
    - Building stronger and more protected “know-how” and “trade secretes”

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Out-Licensing: The Players

- The licensee (Biotech Startup)
  - Stage: Early to mid stage clinical development (usually post Phase-I or Phase-II)
- The sub-licensee (Global BioPharma)
  - Risk vs. Gain assessment (science / clinical / tox / market)
  - Hidden agenda? Shelving?
- The licensee's partners (Licensor, Investors)
  - Licensor represents the long-term / royalty-based view
  - Investors represents the short-term /quick exit view

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Main Out-Licensing Pointers

- Team-up with a veteran lawyer
  - A complex multi-party agreement
  - High risk / high pressure transaction (licensor vs. investor)
- Choose the right partner
  - Personal chemistry with the sub-licensee is critical
  - Anti shelving clauses
- Decide in advance - are you selling the company or licensing a drug
  - What is left after sub-licensing? Is it valuable? Can you afford to continue?

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THANK YOU