



# Innovation & Regulation: Small Company Perspective

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# Opportunity

Innovation is worth it

- Game changing solutions
- Customer Focused
- Nimble
- Higher risk tolerance
- Outsized returns



# Intellectual Property

Typical sources of IP

- University
- Re-purposed technology from private sector



# Intellectual Property

Reasons why IP wasn't licensed to established companies with significant commercial presence

- Technology risks
- Failed tech-transfer
- Existing portfolio
- Internal development
- Lack of differentiation that matters



# Challenges

- Technology
- Manufacturing
- Funding (Livin' on the edge)
- Talent
- Competition
- Regulatory uncertainty (Sometimes "No" isn't the worst outcome)



# Regulatory

Truths of small company innovation

- Capital will NOT be invested without a well-articulated path to market
- A clear and predictable regulatory pathway is essential to ensure a path to market
- Quality regulatory advice early is essential



# Regulatory

Approaches favorable for innovation

- Varied/Graduated license types
  - Autogenous
  - Conditional (Room for expansion?)
  - Commercial
- Flexible
  - Platform
  - Antigen updates





# Thank You



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