Business Development: Identifying R&D Opportunities for Strategic Growth
What is Strategic Growth?
The Process of Evaluating Opportunities

Identification → Assessment → Negotiation → Integration → Continued Development
Identifying and Assessing Opportunities

- Identification
- Assessment
- Negotiation
- Integration

Continued Development
Considerations when Identifying and Assessing Opportunities

- Indication
- Target / Mechanism of Action
- Modality
  - protein/peptide, antibody, small molecule, etc
- Clinical Development Plan
- Manufacturing
- Intellectual Property
- Commercialization
What is the Indication?

- Is there an unmet need?
- What is the potential patient population?
- Are there ways to improve upon current treatments?
- Are there good preclinical models?
- Is it a fit within the organization?
Mechanism of Action and Modality

- Is it novel?
- Existing research and studies?
- Protein / peptide?
- Antibody?
- Small molecule?

- These have important efficacy and safety implications
  - Downstream pathway effects
  - Toxicology profile and off target effects
  - Immunogenicity

- Dosing and administration implications
Development Plan and Manufacturing

- **Development Plan**
  - Is there a known regulatory path?
  - What effect size is anticipated?
  - What risks are anticipated and can they be mitigated?
  - Is it feasible to design an appropriate study?
  - How long and big will the clinical trials need to be?

- **Manufacturing**
  - What is the “cost of goods”?
  - Formulation issues
  - Storage and Stability
Intellectual Property and Commercialization

- Intellectual Property
  - Does it have protection?

- Commercialization
  - Will this be first to market?
  - Best-in-class?
  - How long before generics / biosimilars can enter the market?
  - Is there a current sales force?
  - Will it be acceptable to payers?
Identifying and Assessing Opportunities Requires Experience and Collaboration

- Chemistry / Protein Sciences
- Protein Sciences
- Research
- Toxicology
- PKPD
- Clinical Development
- Regulatory
- Safety
- Manufacturing
- Legal
- Commercial
Thank you