

# **Biotech and Pharma M&A and Collaborations: *Protecting the Deal and Preserving Your Upside***

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# Biotech and Pharma M&A and Collaborations: *Protecting the Deal and Preserving Your Upside*

- ‘One for You, Two for Me...’: *Protections Against (i) Paying Too Much and (ii) Getting Too Little*
- ‘Getting with the Program’: *Protecting the Development and Commercialization of the Product*
- ‘You’re Going the Wrong Way!’: *Protections Against Disalignment*
- ‘Pick Your Medicine!’: *Transaction Structures*
- **Discussion Questions**

# Biotech and Pharma M&A and Collaborations: *Protecting the Deal and Preserving Your Upside*

- ‘One for You, Two for Me...’:  
*Protections Against (i) Paying Too Much and (ii) Getting Too Little*
  - Issue: Biotech wants to receive fair value, while big pharma wants to make sure it doesn’t pay too much too soon
  - Protective Actions and Provisions:
    - Auctions and Bidding Wars
    - Cash Payments
    - Caps on Development and Marketing Budgets
    - Payment Reductions
    - Termination

**‘One for You, Two for Me...’:  
*Protections Against (i) Paying Too Much and  
(ii) Getting Too Little***

- ***Auctions and Bidding Wars***
  - Create Competition in Terms of Money, Speed and Effort
  - Need for Bidder to Distinguish Itself
  - Criteria and Process for Selection of Winner

**'One for You, Two for Me...':  
Protections Against (i) Paying Too Much and  
(ii) Getting Too Little**

- ***Cash Payments***
  - Smaller Up-front Fees
  - Contingent Value Rights in M&A
  - Smaller but More Milestone Payments
  - FTE Reimbursement for R&D Work
  - Equity Investment

**‘One for You, Two for Me...’:  
*Protections Against (i) Paying Too Much and  
(ii) Getting Too Little***

- ***Caps on Development and Marketing Budgets***
  - Caps on Spending Amounts
  - Limits on Number of Years
  - Treatment of Overruns
  - Mechanism for Annual Resets

**‘One for You, Two for Me...’:  
*Protections Against (i) Paying Too Much and  
(ii) Getting Too Little***

- ***Payment Reductions***
  - Royalty Reductions for Generic Competition, Competitive Products and Third Party Royalties
  - Reimbursement of Up-Front Fees or Milestone Payments for Development Delays or Regulatory Problems
  - In M&A, CVR Payments can be in Tiers Depending on Product Achievements

**‘One for You, Two for Me...’:  
*Protections Against (i) Paying Too Much and  
(ii) Getting Too Little***

- ***Termination***
  - Ability to Terminate and Cease Further Investment
  - Reimbursement Upon Termination for Specific Reasons
  - Effects of Termination

# Biotech and Pharma M&A and Collaborations: *Protecting the Deal and Preserving Your Upside*

- ‘Getting with the Program’:  
*Protecting the Development and Commercialization of the Product*
  - Issue: Biotech wants to see its technology developed and commercialized, but its partner will want flexibility to match its obligations to future events and assessments of product potential
  - Protective Provisions:
    - Diligence Efforts
    - Monitoring Progress
    - Ensuring Success
    - Remedies for Diligence Failures

# **‘Getting with the Program’: *Protecting the Development and Commercialization of the Product***

- ***Diligence Efforts***
  - Commercially Reasonable Efforts
  - Specific Diligence Provisions
  - Timetables for Achievements

# **'Getting with the Program': *Protecting the Development and Commercialization of the Product***

- ***Monitoring Progress***
  - Joint Committees
  - Periodic Reporting
  - Notification Requirements
  - In M&A, Board Committees

# **‘Getting with the Program’: *Protecting the Development and Commercialization of the Product***

- ***Ensuring Success***
  - Non-Competes
  - Tie-Breaking Votes
  - Dispute Resolution and Escalation
  - In M&A, Governance Agreement

# **‘Getting with the Program’: *Protecting the Development and Commercialization of the Product***

- ***Remedies***
  - Penalties for Delays
  - Termination Rights
  - Rights Reversions

# Biotech and Pharma M&A and Collaborations: *Protecting the Deal and Preserving Your Upside*

- ‘You’re Going the Wrong Way!’: *Protections Against Disalignment*
  - Issue: Biotechs use the deal to grow capabilities and reputation, and big pharma use the deal as strategic building block
  - Protective Provisions:
    - Downstream Rights
    - Lead Party Roles and Responsibilities
    - Exclusivity
    - Ex-Program Activities
    - Quids

# ***‘You’re Going the Wrong Way!’: Protections Against Disalignment***

- ***Downstream Rights: ‘Who’s got the wheel?’***
  - Manufacturing and Supply
  - Co-Development and Regulatory Filings
  - Co-Promotion

## ***‘You’re Going the Wrong Way!’: Protections Against Disalignment***

- ***Lead Party Roles and Responsibilities: ‘Don’t panic, I’m in charge now’***
  - Niche Indications for Biotech
  - Prioritization of Indications, Products, Territories and Supply
  - Regulatory Interface
  - Booking of Sales

## ***‘You’re Going the Wrong Way!’: Protections Against Disalignment***

- ***Exclusivity: ‘What’s mine is mine and what’s yours is mine’***
  - Technology and Product Scope
  - Duration can be R&D Term or Commercialization
  - Exceptions for Internal or Third Party Programs (Carve-outs)

## ***‘You’re Going the Wrong Way!’: Protections Against Disalignment***

- ***Ex-Program Activities: ‘I’m committed, but can I see other people?’***
  - Use of Collaboration Technology Outside of Program
  - Return of Ex-Program Information for Program
  - Buy-In Rights
  - Royalties or other Reward-Sharing Mechanism

# **‘You’re Going the Wrong Way!’: *Protections Against Disalignment***

- ***Quids: ‘I’ll trade ya... no backsies!’***
  - Timing of Selection
  - Selection Process or Fix in Agreement
  - Stage of Product and Capabilities Needed
  - Scope of Rights from Co-Promote to Book Sales
  - Independence (or Not) from Collaboration
  - Co-Termination with Collaboration

# Biotech and Pharma M&A and Collaborations: *Protecting the Deal and Preserving Your Upside*

- ‘Pick Your Medicine!’: *Transaction Structures*
  - Issue: How to select the best structure for:
    - Acquisitions
    - Licenses
    - JV’s
  - Key considerations in JVs
    - Structure
    - Management

# *'Pick Your Medicine!':* Transaction Structures

## ACQUISITIONS

### Benefits:

- Unilateral management control over the business
- Business is consolidated into the Company's "Business Processes" - planning, reporting, resource allocations, etc.

### Hurdles:

- Premium paid for control
- Management time to effectively integrate acquisition into the business
- Ability to retain key employees
- Short term earnings issues may be more pronounced versus alternatives

# *'Pick Your Medicine!':* Transaction Structures

## LICENSES

### Benefits:

- Access specific technology or compounds with no additional baggage
- Reasonably straight forward
- Relatively high level of control over asset

### Hurdles:

- Competitive marketplace has driven the price of these transactions up
- Level of retained rights desired by licensor

# *'Pick Your Medicine!':* Transaction Structures

## JOINT VENTURES

### Benefits:

- Access to assets/expertise that are “not for sale”
- Expand into market segments which complement core business - without the distraction of an acquisition
- Leverage internal and partner’s expertise

### Hurdles:

- Increased management time required vs. outright ownership
- Divergent operational/financial goals need to be reconciled between partners
- Historically, life span of a joint venture is generally less than 10 years

# 'Pick Your Medicine!': Transaction Structures

## JOINT VENTURES

### Key Considerations in Structuring Joint Ventures:

- **JV Competes** - Avoid the JV directly competing with one or both of the parent companies
- **Asymmetrical Value and Profits** - Equal value going in and equal value coming out of the JV -- 50/50 JV vs. asymmetrical profit splits
- **True-ups** - Avoid “true-ups” or retroactive adjustments of initial contributions
- **Insurance** - With large deductibles, insurance can provide protection and alignment of objectives, up to a point
- **Window Period** - Avoid finite horizons

# 'Pick Your Medicine!': Transaction Structures

## JOINT VENTURES

### Managing the Joint Venture:

- When the JV structure includes.....
  - JV competes
  - Profit splits asymmetrical
  - True-ups
  - Insurance
  - Window period
- ...the partner management costs increase substantially
- The value now must consider the increased cost of “parent management”
- This may lead to re-evaluation of “strategic value” of the JV structure

# Biotech and Pharma M&A and Collaborations: *Protecting the Deal and Preserving Your Upside*

## *Discussion Questions*

- Protective Ways to Choose a Partner
- Protection Through Due Diligence: Hot Areas
- Protections Against being Acquired by Your Collaboration Partner

# ***Discussion Questions***

- ***Protective Ways to Choose a Partner***
- Existing Relationships
- MTAs
- Feasibility Studies
- Scientific Alignment
- Cultural Fit

## ***Discussion Questions***

- ***Protection Through Due Diligence:  
Hot Areas***
- Patents and other IP
- Other Collaborations and Licenses
- FDA/Regulatory
- Equity/capitalization
- Litigation/Risks
- Change-in-Control/Approvals

# ***Discussion Questions***

- ***Due Diligence***

- CDAs
- Focus on IP and Regulatory Areas
- Understand Encumbrances Created by Other Deals, in M&A
- Representations and Conditions Tailored to Specific Facts and Issues

# ***Discussion Questions***

- ***Protections Against being Acquired by Your Collaboration Partner***
- Standstill Provisions
- Equity Investments
- Changes in Valuation from Deal
- Post-Signing New Programs and Deals