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# Pharma - Biotech Collaborations: Optimizing Success, Minimizing Risk and Maintaining Alignment

Presenter:

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# Biography



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- Randall B. Sunberg is a partner in Morgan Lewis's Business and Finance Practice, vice chair of the firm's Life Sciences Interdisciplinary Group, and co-chair of the firm's Life Sciences Transactions Practice.
- Mr. Sunberg's clients range from early-stage biotechnology start-ups to global pharmaceutical companies, as well as specialty pharma, medical device, and other technology companies. His clients also include private equity, venture capital, and investment banking firms focused on the life sciences industry. He advises these clients on a variety of mission-critical transactions, including negotiation and structuring of acquisitions, divestitures, joint ventures, corporate partnering, licensing and other complex collaborations, and the equity investments and other securities matters that often accompany such transactions.
- Mr. Sunberg has spoken on the subjects of mergers and acquisitions, strategic alliances, and licensing and collaboration transactions in the United States at BIO Annual Meetings and LES Annual Meetings, in Canada at BIOMedex, and in China at BIOForum, as well as at other life-sciences-related conferences and as guest lecturer at the Rutgers Business School MBA Biotechnology Commercialization Concentration.

# **Pharma - Biotech Collaborations: Optimizing Success, Minimizing Risk and Maintaining Alignment**

***Protections Against (i) Paying Too Much and (ii) Getting Too Little***

***Protecting the Development and Commercialization of the Product***

***Protections Against Disalignment***

**Discussion Questions**

# Pharma - Biotech Collaborations: Optimizing Success, Minimizing Risk and Maintaining Alignment

## *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:
  - a. Auctions and Bidding Wars*
  - b. Cash Payments*
  - c. Caps on Development and Marketing Budgets*
  - d. Payment Reductions*
  - e. Termination*

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## *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

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## *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

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## *Caps on Development and Marketing Budgets*

- Caps on Spending Amounts
- Limits on Number of Years
- Treatment of Overruns
- Mechanism for Annual Resets

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## *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



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## *Termination*

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

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## *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:
  - a. Diligence Efforts*
  - b. Monitoring Progress*
  - c. Ensuring Success*
  - d. Remedies for Diligence Failures*

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## *Diligence Efforts*

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

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## *Monitoring Progress*

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

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## *Ensuring Success*

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

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## *Remedies*

- Penalties for Delays
- Termination Rights
- Rights Reversions

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## *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:
  - a. *Downstream Rights*
  - b. *Lead Party Roles and Responsibilities*
  - c. *Exclusivity*
  - d. *Ex-Program Activities*
  - e. *Quids*

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## *Downstream Rights*

- Manufacturing and Supply
- Co-Development and Regulatory Filings
- Co-Promotion



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## *Lead Party Roles and Responsibilities*

- Niche Indications for Biotech
- Prioritization of Indications, Products, Territories and Supply
- Regulatory Interface
- Booking of Sales

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## *Exclusivity*

- Technology and Product Scope
- Duration can be R&D Term or Commercialization
- Exceptions for Internal or Third Party Programs (Carve-outs)

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## *Ex-Program Activities*

- Use of Collaboration Technology Outside of Program
- Return of Ex-Program Information for Program
- Buy-In Rights
- Royalties or other Reward-Sharing Mechanism

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## *Quids:*

- 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

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## *Protective Ways to Choose a Partner*

- Existing Relationships
- MTAs
- Feasibility Studies
- Scientific Alignment
- Cultural Fit

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## *Protection Through Due Diligence: Hot Areas*

- Patents and other IP
- Other Collaborations and Licenses
- FDA/Regulatory
- Equity/capitalization
- Litigation/Risks
- Change-in-Control/Approvals

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## ***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

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## Questions and Answers