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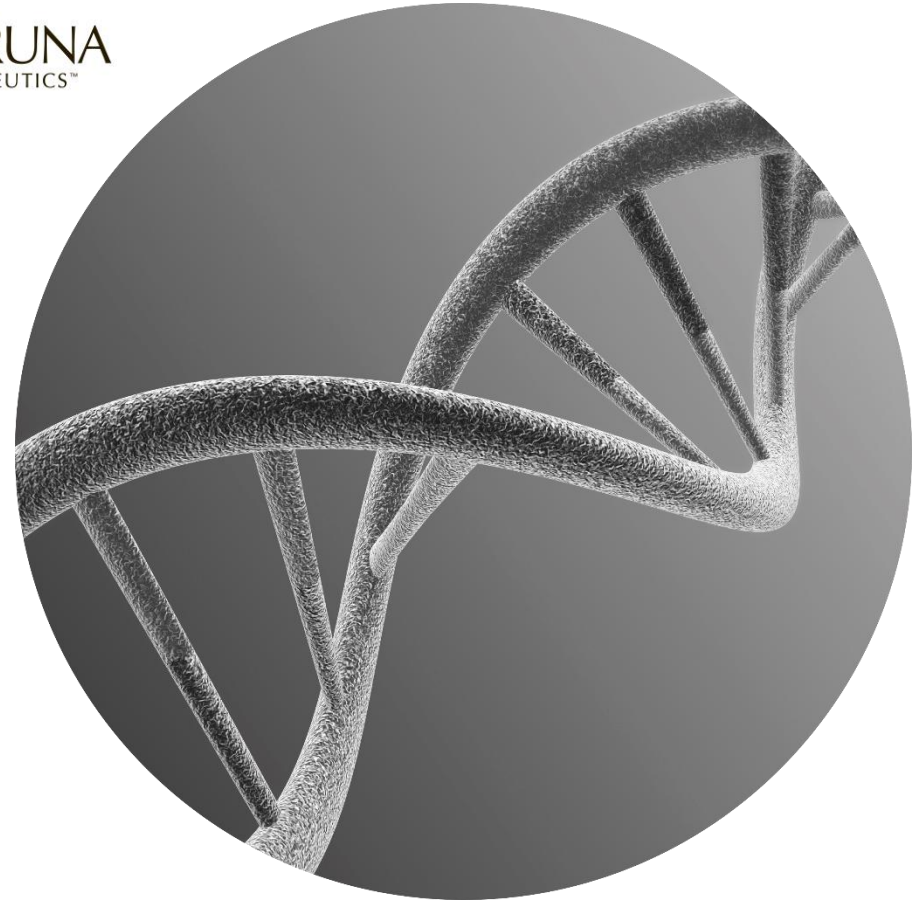

Advanced Life Sciences Licensing Agreements

Presented by:

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Polling Question #1

Who is in the audience?

A. In-House Counsel

B. Outside Counsel

C. Just here for the CLE

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Importance of Life Sciences Deals

- Partnering to bring innovative drugs to market has always been critical to success for both small and large companies
  - Partnered assets make up greater than 50% of the R&D pipeline in most big pharma, not counting alliances to do early research
  - Biotechs often need partners to complete development and/or to commercialize
- Due to the high level of cost and risk in R&D, the long timelines to success, and the complex regulatory and IP framework, life sciences deals need to cover certain unique areas in addition to standard licensing agreements
- Can also extend to natural products in the supplement market

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Overview

- Research Plans
- Due Diligence
- Risk Allocation
- Transitioning Pharmaceutical Products/Programs
- Monetary Considerations
- IP Considerations
- Deal Structures
- Governance
- Final Dispute Resolution
- Post Deal Considerations & Implications

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Research Plans

- Getting started
- Deciding who to partner with
- Identify the objectives of collaboration

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Polling Question #2

Have you ever negotiated a Life Sciences Transaction?

A. Yes

B. No

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Due Diligence

- Diligence obligations are important to a licensor granting an exclusive license to encourage licensee's performance of development and/or commercialization activities in order to maximize the economics it receives under license
- Licensee diligence is important to understand scope of licensed rights
- Licensee is generally concerned with overly burdensome diligence obligations imposed by licensor that may give licensor right to terminate if such requirements are not met
- Diligence provisions typically heavily negotiated, and there is a wide range of licensor-favorable to licensee-favorable provisions to consider
- Diligence obligations are often mandatory if partnering with an academic or not-for-profit entity but scope and obligations often vary depending on the type of licensing entity

Kinds of Post-License Diligence Obligations

- Obligation to perform research and development activities; can be dependent on licensor's timely transfer technology/know how/IP
- Obligation to conduct development activities to obtain data sufficient to obtain regulatory approval
- Obligation to seek or obtain regulatory approval
- Obligation to commercialize once regulatory approval is achieved
- Obligation to prosecute, maintain, defend and enforce patents
- Obligation to meet certain milestones for research and development activities within a certain time period

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Risk Allocation

- General approach
- How to determine allocation of risk
  - Control
  - Which party is/or will profit more
  - Which party has invested/or will invest more resources
- Indemnification for past conduct
- Indemnification for post-termination conduct
- Survival of indemnities

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Transitioning Pharmaceutical Products / Programs

- **Not just a license at issue, but the transfer of all rights to a product or research program (complexity depends on stage of product / program)**
  - Know-how / data
  - Biological materials
  - Regulatory approvals
  - Third-party contracts
  - Manufacturing rights

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Monetary Considerations

- **From a legal perspective, make sure you cover the exact timing for each type of payment, and clear guidelines for their calculation:**
  - Upfront Payments
    - Cash
    - Equity purchase
  - Milestone Payments
    - Achievement of research, development, approval, sales milestones results in specified payments.
    - These payments work best if they anticipate changes in approval strategy and law

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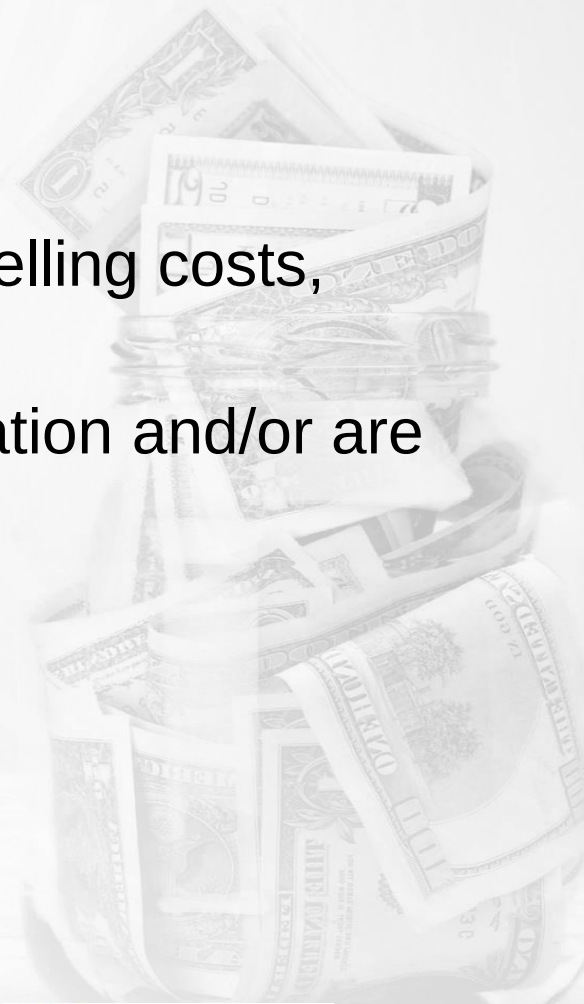
Monetary Considerations

- **Royalties**
  - Most often paid on net sales of specified products
  - Standard deductions for amounts invoiced to purchasers but paid to third parties
  - Consider combination products, product bundling treatments
  - For medical devices, consider portion of value attributable to licensed product
  - Offsets for third party payments, reductions for lack of patent coverage, compulsory licenses granted, and other necessary licenses

Monetary Considerations

- **Profit Sharing**
  - More complex than royalty structure
  - Requires defining how profits are calculated, including selling costs, costs of product-related litigation, etc.
  - More common when parties have an extensive collaboration and/or are co-promoting products



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IP Considerations

- Background IP vs. Foreground IP
- Determining allocation of ownership of IP
- Joint ownership issues
  - Use and licensing
  - Accounting obligations
- Licensee protections of IP license in event of licensor bankruptcy
- Exclusivity versus Freedom to Operate

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Termination

- Material Breach
- Convenience
- Bankruptcy
- Other Grounds:
  - Patent Challenge
  - Change of Control
  - Safety Issues; Certain Regulatory Actions
  - Antitrust Issues
  - Force Majeure

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Termination

Mechanics

- Cure periods
- Country-by-country and/or product-by-product
- Types of breaches
- Tolling of termination

Important considerations

- Be specific
- Self-executing v. transition/termination agreements
- Who walks away with what? (IP, 3rd Party contracts, materials)
- Allocating post-termination risks and responsibilities

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Governance

- **For Joint Ventures, Governance Needed to manage the relationship between the parties and to ensure clear decision- making process**
  - Joint Steering Committee
  - Tie Breaker Vote
    - One party to the deal (Chair or Funding Party)
  - Sub-committees for specific activities
    - Joint Research Committee/Joint Project Team
    - Specialty sub-committee for IP or regulatory issues
    - Who has ultimate decision making authority?
    - Membership and obligations of each party

Governance

- Provide for governing committees and project teams to conduct specific activities
- A senior committee with subcommittees tasked with specific roles
- Final decision-making authority
- Regular meetings
  - Shared meeting minutes
  - Regular updates to product development plans

Governance Committee Structures

- Committees may reflect pharma partners' internal organizational structure and standard practices
- Specified number of representatives per committee
- Frequency, nature and location of meetings
- Meeting agendas
- Minute-taking obligations by each partner
- Chairperson(s)
- Alliance Managers

Governance Committee Decision-Making

- Decision-making by consensus or unanimity, particularly at junior committee level
- Senior committee level, one party may have final decision making rights on all, or certain specified, types of matters
- Senior committee may be required to submit open issues to designated officers of each party
- Open issues may be submitted for final dispute resolution; allocation of final decision-making rights

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Final Dispute Resolution

- Court
- Mediation
- Arbitration
- Call in experts to resolve technical disputes

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Arbitration & Mediation Considerations

- **Arbitration and Mediation Clauses**
  - **Confidentiality**
  - **During the pandemic arbitration and mediation have not had the same barriers to resolution as many court cases have had due to court closures.**

    <u>The following questions should be considered:</u>

    - Would my client benefit from arbitration or mediation in the current climate?
    - Would my client benefit from the confidentiality of an arbitration or mediation proceeding?
    - Would my client benefit from an arbitration or mediation in a particular jurisdiction?

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Polling Question #3

What is the most difficult part of any life science licensing agreement?

A. Choosing a partner
B. Drafting the agreement
C. Choosing the “deal toy”
D. Sticking to the terms of the agreement.
E. Remembering what you meant during negotiations when the agreement is eventually litigated

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Post Deal Considerations & Implications

- **Remember to consider post closing considerations and implications while negotiating a transaction**
  - Discuss post execution commitments with functional heads, including:
    - conduct of joint trials
    - supply commitments
    - commitments that may impact regulatory strategy
  - consider who your alliance manager and JSC reps will be
  - consider company bandwidth and whether additional hires will be needed immediately post-closing

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THANK YOU!