Advanced Business Development Course

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Biotechnology Industry Organization

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Cooley LLP

- Practice exclusively focused on representing public and private life sciences companies in strategic corporate partnering and intellectual property commercial transactions
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Our Session Today

- Broad overview of structuring and contract considerations for Biotech/Pharma collaboration agreements
- “Term Sheet” level treatment with deeper dives into specific areas

Areas of Focus

- Focus on the following key areas:
  - What rights are granted (scope of license/retained rights) and what is the "price"?
  - Provisions you <u>will</u> re-read later and may regret
  - Other selected topics – diligence, exclusivity, governance, etc.

The Big Picture

- Why partner?
- Financing needs / leverage?
- Retaining rights to preserve <u>future</u> deals, trade sales and other options
- Board and investors interests
- What is “market”?
- What does your Partner want?
- Objectives always will shape deal structure – there is no single approach
- Is this deal a “stepping stone” to an acquisition?

Constructing the Deal and Retaining Value

What is the Overall Deal "Story"?

- Every deal has a "story" and is driven by key underlying corporate objectives on both sides
- Breadth of collaboration
- Market opportunity and product positioning
- Risk and stage – risk reduction/value inflection points
- Strengths, weaknesses and competition

What is "in" the deal?

- The starting point of negotiations, but term sheets can be vague or incomplete
- What rights are granted?
- Key terms: Licensed Product and Licensed IP
- Beware of "deal creep"
- Overall objective – match rights granted with economics
- There are so many different possible deal "sizes" you want to be sure you and your partner are clear:
    - Single molecule/single form of administration (e.g., IV, topical, ophthalmic, pulmonary)?
    - Single molecule in all formulations?

Retaining Rights?

- Where can you (or need to) retain rights to achieve your company's underlying objectives?
- Important to preserve value, ability to do other deals, sell the company, and provide "exit" for investors
- The usual suspects
  - Not licensing all rights (think rights as a bundle) – product, indication, territory?
  - Development, manufacturing, and/or commercialization?
- How do retained rights fit into the deal "story"?
- Need to match the scope of the deal with the value proposition

Retained Rights

- How NOT to … "sell the company without selling the company"
- What works to keep value?
  - Product rights granted – current; future
  - Field – therapeutics and diagnostics?
  - Territory
  - Indication-splitting – its own topic
- Focus on the creation of and rights to future IP – both inside and outside of the collaboration

Licensed Product

- Product Scope:
  - Single compound? Backups?
  - All molecules covered by specified patent(s)?
  - All molecules active against a specified target?
    - Is that *all* molecules? Small molecules vs. biologics? Antibodies? Vaccines? Agonists vs. antagonists?
    - Can a specified level of activity (assay results) be used in the definition?
    - If it is all molecules “created” during a research program, does that mean “invented” (patent filing) or “made” or “recognized” (run through an assay)?
- Slippery slope from defining “Product” to hidden exclusivity/non-compete obligation

Licensed Product Definition

- May be defined in terms of:
  - Attributes of the product or process
  - Relationship of product or process to Licensee
  - Relationship of product or process to Licensed Technology
- Examples:
  - "Any product that incorporates a molecule that binds Target X"
  - "Any human pharmaceutical product"
  - "Any product that incorporates a molecule identified by Licensee in the course of practicing the Licensed Technology"
  - "Any product developed and sold by Licensee for use in the Field"
  - "Any product (a) the manufacture, use or sale of which would, but for the license granted herein, infringe a claim of a Licensed Patent or misappropriate Licensed Know-How or (b) that incorporates, uses, is based upon or otherwise is conceived, developed or reduced to practice using any of the Licensed Technology"

Field

- Will there be any limits?
- Therapeutic vs. diagnostic products?
- All delivery routes (oral, intravenous, systemic, etc.)?
- Particular diseases or medical conditions (beware of Amgen/Ortho issues for substitutable formulations)?

Territory

- Any limitations?
- Geographical limits
  - Watch for ambiguity in territory definition
- Implications for dividing on country or regional lines

Licensed Intellectual Property

- A key area to retain value
- How broad is the category of IP licensed to pharmaceuticals
- Existing IP
- Future IP
  - In and out of collaboration?
  - Licensed?
- Acquiror IP
- Generally, all IP owned or controlled by licensor that reads on licensed product

Intellectual Property

- Allocation of IP generated during the collaboration
  - Inventorship by your collaborator – how is ownership assigned and what about each party's right to use this IP (during the term and post-termination)?
  - Do you need to be worried that a collaborator could develop new patents that might block your future development path?
- Third Party IP
  - If acquired during the term who controls and pays?
  - Don't automatically sweep in acquiror IP; consider this issue with potential poison pill implications

Other Retained Rights

- Co-Development
- Co-Promotion
- Splitting Territories
- Splitting Indications

Co-Development

- Can be an attractive way to share risk/return
- Right vs. obligation?
- What do you really mean by co-development?
- Primary approaches (with plenty of variants)
  - Biotech performs pre-defined development activities and is reimbursed by Pharma
  - Biotech opts-into Pharma's ongoing development activities to buy-up royalty
  - Broad sharing of development activities in a fully, risk-shared deal

Co-Development

- Why do it?
  - Biotech retains input into development decisions
  - Maybe some ability to increase economics by risk sharing
  - Biotech obtains access to Pharma's clinical/regulatory expertise and resources
  - Allows Biotech to utilize & grow its own capabilities
- Issues you'll encounter
  - Pharma will tolerate it, but doesn't like it generally – doesn't need the cash and would prefer not to complicate decision-making
  - What control rights?
  - Cash is expensive to Biotech

Co-Development

- Reimbursement is easiest – usually short term participation; key issues are budget, decision-making
- Option is more complicated –
  - When can you opt-in and for what activities?
  - What is the risk premium and what happens to economics – royalty step-up or conversion to profit share?
  - How does decision-making change?
  - Need to consider the opt-out
- Obligation to co-develop/truly risk shared deals

Co-Development

- How do I fund?
  - Own pocket?
  - Sale of equity or loans to Pharma?
- Well, on second thought….opt-out rights
  - Can Biotech opt-out of development rights once Biotech is obligated to conduct activities?
  - When is this right exercisable?
  - What are the economic implications?

Co-Development

- Implementation Issues
  - Global vs. regional development activities
  - Parallel development – safety reporting; regulatory responsibilities
  - Cost allocation for shared territories
  - Decision making issues
  - Rights of use and reference to data and filings
  - Product supply

Co-Promotion

- What do we mean here?
  - A single brand promoted by two different companies
  - One company typically takes lead in establishing strategy (Pharma) and Biotech compensated for its sales effort
- Option vs. obligation
- Distinctions between royalty vs. profit sharing deals

Co-Promotion

- What are Benefits of Co-Promotion?
  - Biotech can leverage the deal to build sales force
  - Biotech can utilize its expertise in "niche" detailing
  - Wall Street value
- What are Problems with Co-Promotion?
  - Pharma does not particularly like it
    - Selling drugs is what Pharma *does*
    - Would prefer not to train or coordinate with Biotech
  - A sales force is not always an asset for a Biotech
    - Once established, a sales force needs products
  - Potential for overlapping efforts & inconsistent messages

Co-Promotion

- Biotech option or obligation?
- In the option scenario
  - When is the right exercisable?
  - How do parties allocate sales efforts (by territory, physician group)?
  - How is compensation determined – by detail? FTE? Stepped-up royalty?
- What terms are negotiated now vs. agreed later?
- More complication in the “obligation” scenario

Splitting Territories

- Can be an attractive option for Biotech and for a locally-focused Pharma partner
- A few key considerations at the term sheet stage -
  - Impact on economics and control rights for aspects of the "global" plan
  - Cross-licensing of IP and how will data be shared
  - Operational issues – common or multiple sources of product supply? Ability to run trials in the other party's territory?

Splitting Indications

- Indication splitting limits license to particular diseases or conditions
- It can be done, but complicated
  - Is the product substitutable between indications?
  - Separation of product in the market
  - Contractual/financial engineering

Splitting Indications

- Pros
  - Can increase probability that the product will be developed for multiple indications
  - Can find best suited partner for each indication
  - Can retain right to develop drug for niche indication while partnering indications that require more expensive clinical trials and extensive commercial operation
- Cons
  - Off-label sales
    - Once approved for one indication, MDs can prescribe for any indication
    - Need to make sure that not earning profits for sales in other party's field
    - Simplest if unique formulation or mode of administration
- Potential disputes over field
- Safety and pricing issues are not indication-specific

Economic Terms

“What is the Price”?

Economic Considerations

- Royalties
  - Typically in earlier stage or less collaborative deals
  - Straightforward administration
  - Economics can be comparable to profit sharing
- Upfront and Milestone Payments
  - Development and/or commercialization
- Profit Share
  - Typically in "risk shared" deals co-funding
  - Detailed cost accounting
  - Allocation of losses
- Other Forms of Consideration
  - Equity (at a premium?)
  - Loans (convertible, repayable, forgivable, creditable?)

Initial Thoughts

- You won’t get what you don’t ask for, but credibility is important
- Who shows their hand first?
- Your first proposal is the ceiling – it’s all downhill from there
- Competition is the key – either apparent or actual
- Interplay with M&A proposals?

Upfront License Fees

- Up-Front Payment
  - The price of entry
  - *Watch:* revenue recognition and involve your finance team
- What can you ask for?
  - Willing buyer/seller
  - The role of comparables
  - Other proxies – R&D expenses

Milestone Payments

- Rationale:
  - Delayed “license fees” – risk mitigation for licensee
  - Reward for success that shows value of the licensed IP
- Typically tied to development and commercial events:
  - Research milestones (defined per deal)
  - Filing of an IND
  - Initiation of a clinical trial (e.g., Phase II)
  - Filing and approval of NDA or BLA
  - Commercial launch
  - Sales thresholds

Milestone Payments (cont'd.)

- Milestone triggering events must be carefully defined (it's money after all)
  - Clinical milestones – what is "initiation" of trial (usually dosing)?; when is a trial "complete" (e.g., submission of final report)?
  - Approval – include pricing approval where applicable?
- Appreciate the various payment scenarios
  - One or more products?
  - Different formulations?
  - By indication?

Milestone Payments (cont’d.)

- Multiple products and indications
  - What is considered a new product?
- Back-up products
  - What if the lead fails – generally exclude prior milestones and continue on with future payments
  - Are milestones due for every back-up product, or only separate 2nd generation products (however defined)?
- Milestone “skipping” protection:
  - Payment of any “skipped” milestones (e.g., for a Phase IIb/III trial) due when next milestone is paid

Royalties

- Payments based on product sales or other commercial use of the licensed IP
- Each party shares risks and rewards of success
- Rate, duration and reductions are highly negotiated though there are some guidelines

Royalties

- Royalty Rate depends on a number of factors:
  - Type of IP licensed (patent claims or know-how)
  - Stage of development when licensed
  - "Value" of IP and Product (perceived vs. real)
  - Comparables can help guide the discussion
  - No substitution for competition

Royalties

- Pay on Product (or use of Product) based on nature of the Licensed IP used
- Capture all uses of Licensed IP?
  - License scope rarely broader than royalty-bearing product definition, at least not intentionally
- Is royalty based solely on patented subject matter?
  - Are products "derived from", "identified through the use of" or "would not have been developed without use of" the Licensed IP?
  - Know-how can be highly valuable, but its use difficult to trace

Calculation of Royalties

- Usually a percentage of "Net Sales" of Licensed Products
  - Important to define Licensed Product clearly
  - "Net sales" – negotiated but some degree of standardization
  - CFO or Controller often involved
  - Licensor's or Pharma's internal standards will impact flexibility

“Typical” Royalty Rates

- What are “typical” royalty rate ranges?
- How do I bridge the gap?
- Market factors
  - Albeit imperfect, it is a market – market conditions may change
  - Deal-specific factors determine where your deal falls in the spectrum
  - Consult advisors (board members, transaction counsel, VCs)

Royalties – Tips

- Seeking "profit share" economics with a substantial royalty
  - Payments begin on launch not when profitability reached
  - No risk of high manufacturing costs or third party royalties
- Tiered Royalties
  - Calibrating royalties to success in marketplace
- Include other forms of exclusivity in the royalty term
  - Examples: Orphan drug exclusivity, data exclusivity, lack of generic competition

Royalties – Tips

- Tiered Royalties
  - Clarify if first tier rate applies to first sales in year, even if total sales qualify for higher tier
    - Example: $1-250 million 10%
    - $251-500 million 12%
    - For sales of $350 million, is the royalty $37 million (250 x .1 + 100 x .12) or $47 million (350 x .12)?
  - If always starts at first tier, consider impact on quarterly financial reporting
  - If payments based on total year sales (same rate applies to all sales), need mechanism for estimating at outset and truing up at end of year

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Areas of Potential Negotiation: Net Sales

- Amounts billed vs. received
- Sale to end user vs. third party purchaser
- Extent of deductible rebates, discounts and commissions
- Taxes and duties that are deductible
- Uncollectible amounts (if based on amounts billed)
- Transportation (outbound, caps)
- Extent of deductible returns and whether recall expenses are included
- Inclusion of combination or bundled Product reduction
- Exclusion of sales of clinical trial supplies or “compassionate use” products
- Non-cash consideration value
- Overall cap on total % deduction allowed or set % to cover all deductions

Other "Net Sales" Concerns

- Upstream "Net Sales" definition
- Upstream (or future) royalty obligations
- Combination products

Royalties -- Term

- Term – usually "greater of" patent life (regulatory exclusivity) or stated period (often 10 years) from first commercial sale in the country
  - Last to expire patent having a "Valid Claim" that covers the Licensed Product or its manufacture or use in country of sale (or manufacture?)
  - Does "Valid Claim" include patent applications? Time restrictions?
- Alternatively, royalty term can last for so long as products are being sold (with some step down)

Royalties -- Term

- Include regulatory and other forms of patent extensions in the royalty term
- Each prong should be country by country-
  - Launch clock should start when launched in the particular country
  - Patent clock should be based on claims in country of sale, with possible extension if patent in country of manufacture has not expired

Royalties – Reductions

- Three common reductions
  - patent expiry,
  - third party payments, and
  - generic entry
- Reduction may shorten the royalty term or reduce the royalty rate

Royalties – Patent Expiration Reductions

- Patent expiry implicates the “patent misuse” doctrine in the US, which is a complicated and detailed topic; also can consult patent and antitrust groups for specific questions
  - Mitigate risk by reducing royalty rate after patent expiration if there is Know-How involved in the license; royalty rate is “blended” across the royalty term to account for both patents and Know-How
  - Separate competition law issues arise ex-U.S., including duration and requirements for know-how licenses

Royalties – Third Party License Payments

- What is included?
  - How likely is third party IP?
  - Product-based or broader?
- If Licensor: try to limit cut back to those license payments made to 3rd parties for IP "necessary to practice" the IP licensed by Licensor
- The "50/50" Rule
  - Deduct 50% of royalties paid to 3rd party
  - Never pay less than 50% of base royalty rate
- Process and control over who obtains third party rights also is important
- Watch correlation of payments – milestones, royalties and "carry forward" of payments in excess of a cap

Royalties – Generic Entry Reductions

- Reduction or elimination of royalties for “generic entry”?
- Generally defined in terms of some threshold of generic entry – is the standard pricing decreases, volume thresholds or a combination
- Definition of generic product is key but may be tough in the case of biologics
- Should not be a product that is enabled by licensee (no authorized generic)
- What happens if a generic proceeds “at risk” and need to address Licensee’s obligation to stop the generic entry (restoration of higher royalty if generic is taken off the market)

Profit Sharing

- A topic worthy of its own presentation
- Several top line thoughts for deal structuring

When Do You Profit Share?

- Opportunity for a “risk-shared” asset
  - Biotech has a clinical stage compound
  - AND a significant cash position (or access to cash)
  - Business strategy of biotech = more fully integrate upstream capabilities
- Typical relationship:
  - Biotech retains co-development, co-promotion obligations/rights in home territory
  - Pharma gets exclusive rights in ROW
  - Operating profits split 50/50 in home territory
  - Royalty on Net Sales in ROW
- Corporate strategy and Wall Street may favor
- Don’t forget about costs and sharing of “losses”

Profit Sharing – Tips

- Establishing the profit share – fixed vs. adjustable
  - Most frequently fixed and tied to development funding
  - Consider adjustments if obligations change – e.g., Biotech opts in to perform development or commercialization activities
- Consider and balance decision-making control and operational responsibilities with profit/loss allocation
  - Who will carry out and finance activities – e.g., manufacturing?
  - Does decision-making control align with financial impact?

Profit Sharing – Tips

- Don't forget about "shared" costs in deals with profit sharing and royalty split by territory
  - Will certain shared costs be allocated between the profit-sharing territory and royalty territory?
  - Many cost categories potentially could be shared – clinical development costs used for a core dossier; third-party IP acquisition/license costs; manufacturing costs?

Profit Sharing – Tips

- What flexibility might Biotech need given potential financing limitations?
  - Right to opt-out to a reduced profit share or royalty arrangement? By territory?
  - Is commercialization an obligation or an option?
  - Financing by Pharma – advancing launch costs with P&L "payback" royalty

Profit Sharing – Tips

- Address significant P&L items at the term sheet stage
  - Launch costs
  - Sales force expenditures when parties are co-promoting
  - Cost of goods where a party is supplying product or product components

Terms You Will Re-Read –

Dos and Don'ts

License Grants

- If there is a dispute, you will re-read this language countless times
- The definitions and grant should be as clear and precise as possible
- Read the definitions in the context of how they are used
- Pay particular attention to the term, any <u>surviving</u> research licenses particularly

Third Party Rights – Sublicenses and Assignment

- Two related but distinct concepts
  - The further grant of license rights to a third party vs. assignment of the license agreement itself
- The ability to transfer rights is critical as licensees generally will partner or further license IP; every biotech should expect (and perhaps hope) to be acquired some day
- It is important to be clear in the license agreement regarding sublicensing and assignment as the background legal rules (if the contract is silent) are not always clear

General Sublicensing Issues

- May all or a subset of rights be sublicensed?
  - Licensor's prior consent (not to be unreasonably withheld)?
- Can a sublicensee grant further sublicenses?
- If sublicensing is permitted, what (if any) restrictions apply –
  - All or certain rights?
  - Time or territory-based limits?
  - Identity of the sublicensee – independent contractors, partners, competitors?
  - No "naked" sublicenses
- What about affiliates?

Impact of Sublicensing

- Economic terms
- Flow-through and application of license agreement terms to a sublicensee
- Disclosure of confidential information and IP generation
- Risk allocation and obligation of the licensor to remain responsible for payment and sublicensee activities
- Consequences of termination
- Pay careful attention to the “upstream” agreements … what rights can <u>you</u> license and what economics are owed to <u>your</u> licensor

Sublicensing Economics

- How does licensor receive an economic benefit from licensee's grant of a sublicense?
- Fundamental approaches
  - Same royalty rate applies to sales by licensee and sublicensees (licensee keeps any excess collected from sublicensees) and licensor receives a percentage of other amounts paid by sublicensees
  - Licensor receives a percentage of all amounts paid by sublicensees (i.e., "sublicensing revenue")
- Definition of "Sublicensing Revenues" is highly negotiated
  - Should include all consideration for the sublicense granted – upfront, milestones, royalties, non-cash consideration, premium on equity purchase, and low or no interest loans
  - Should exclude payments for other goods or services - equity purchase at fair market value, loans at market rates, research funding payments, or reimbursement for patent expenses

Assignment

- A "deal breaker" issue is today's environment
- Common scenarios –
  - Assignment in connection with a change of control transaction - sale of entire business, merger or asset sale (generally, always should be assignable)
  - Spin off transactions?
  - Affiliate transfers?

Assignment

- Need right to assign agreement in an M&A transaction:
  - "the entire company"… OR …. "that part of such Party's business to which this Agreement relates"
  - Allow assigning to affiliates for acquiror restructuring
  - Still see significant restrictions – *particularly in collaborative research work*
- Right to disclose agreement to potential acquirers – what about targets, lead candidates, etc.?
- Carve out M&A from rights of first refusal and negotiation to avoid unintended M&A block
- Pay particular attention to the "Change of Control" definition

Change in Control Consequences

- A strong company with a hot product can insist on there being no effect.
- More commonly:
  - Adjust terms only in the event of a buy-out by a big company or competitor of the licensee
  - Then adjust control rights and information flow; do not change economics
  - Terminate co-promotion rights if the product has not yet launched?

Termination

- Frequently under-negotiated
- It's at the back of the agreement and no one wants to think about it (or, left out of the term sheet completely)
- Negotiate this as a business point (not boilerplate)
- The scenarios –
  - Voluntary termination by Pharma licensee (Maybe)
  - Material breach
- Consequences are the key

Termination – Voluntary by Licensee

- Can the license terminate at its discretion?
  - My advice: Yes after a minimum period of time. You do not want a “partner” who holds a license under duress.
  - But be careful about country-by-country termination. Could this be a way to avoid royalties?
- Easy way out or the lesser of two evils
- Assess time periods in which the company or the program is particularly vulnerable
- Limit window for exercise
  - Repartnering without excessive loss of time to market or upheaval (e.g. pre-launch phase)
- Product-by-Product termination?
  - Caution: termination of lead program in favor of back-up program only for cause
  - Consequences-acceleration of payments; long notice period.

Termination – Voluntary by Licensee

- Licensors generally should start by proposing that the program be returned to the original licensor *in its then-current condition*
- Need to address issues of grant-back licenses, know-how and regulatory transfer, interim supply, etc.
- Is a royalty due under the grant-back license? This may depend on the stage of development. (Or perhaps just “no” because the program is now seen as damaged goods.)

Termination – Material Breach

- This is really a discussion about breach and remedies
- Can be very frustrating
- I believe that "the punishment should fit the crime"
- But many Pharma licensees work hard to make the consequences of material breach overwhelming

Termination – Material Breach

- If the *licensor* breaches, the idea that all licenses should become royalty-free is widespread but absurd
- The damage caused by the breach may be a small fraction of the value of the royalty stream
- Just provide for money damages in this case, or a partial reduction in royalties (credited against actual damages)?
- Do sublicenses terminate as well? If not, then the licensor may not get the product back

Other Selected Topics

- Diligence
- Exclusivity
- Governance
- Option-based deals

Diligence

- Licensors are frequently unhappy when programs get "lost" inside Pharma – slowed down, sidetracked, or just the victim of bureaucracy
- When might incentives not match?
- But "diligence" provisions are perhaps the most difficult to negotiate
  - Future events are unpredictable. For all kinds of reasons, licensees have a very limited ability to commit their future resources

Diligence

- Text alone without any detail ("Commercially Reasonable Efforts") may not mean much. Consider:
  - The weakest CRE language could arguable mean no effort at all. What if it is "commercially reasonable" to do nothing?
  - Consider reference to an "industry" standard rather than a standard based on the normal practices of the particular licensee. Or even the "reasonable best practices" of the industry?
  - Require the application of CRE "within an active and ongoing program"?
- There is no substitute for choosing the right partner

Diligence

- Best to be as specific as possible:
  - For example, attach a Development Plan and obtain a commitment to carry it out
  - Or obtain a commitment to the first one or two clinical trials that can presently be defined
  - A minimum spending level? (A minimum might be very meaningful, even if it is well below expected spending levels)
  - Minimum launch effort (sales force size)?

Exclusivity

- The licensor is almost always exclusive to the licensee, just by reason of granting an exclusive license
- Does this work both ways?
- Is it OK for the licensee Pharma to have a directly competitive program underway while still practicing your license?
- This issue should almost always be discussed and negotiated, whether the answer is “yes” or “no”

Exclusivity

- If the relationship will be mutually exclusive, then the boundary of this exclusivity needs to be carefully defined
  - A class of molecules (e.g., a particular mechanism of action)?
  - What duration? (For example, only during a “research term”, or the life of the agreement?)
  - Is competitive research OK, but not clinical development?

Exclusivity

- Key argument for exclusivity:
  - Nothing will *undermine trust* in a working relationship faster than the suspicion that your "partner" is pursuing a separate agenda
- If the licensee *is* permitted to have a directly competitive program, now you really need to re-focus on economics, licenses, timelines & diligence provisions with this in mind
- Address change of control implications; this cannot become an acquisition poison pill

Governance

- Included as part of every collaboration agreement for input or decision making over operational issues (not all disputes under the agreement)
- Typical flow -
  - Unanimous decisions at committee level
  - Escalation process
  - Final decision by: one party (specific issues or overall), independent expert, mediation, etc.
  - Goal: Process for rapid and effective resolution of disagreements arising from collaboration

Governance (cont'd.)

- Final decision by one party
  - Expect to see unilateral decisions by the "funding" party (the "golden" rule)
- Veto rights for specific decisions
  - Delay of development program
  - Abandonment of product/indication/major market
  - Decisions that "adversely affect" the vetoing party's interests in its retained territory
  - Regulatory compliance
- Independent expert
- Mediation/Arbitration

Option-Based Deals

- Most every collaboration agreement is an “option” in that Pharma can terminate for convenience
- Other possible option structures
- “Shared” risks and rights / control prior to option exercise
- Locking in value and pricing economics

Asset-Specific Transactions

- Increasing consideration of “asset-centric” transactions, involving collaboration components and partner right to acquire assets at specified time points
- Collaboration arrangement PLUS put/call rights to sell/ acquire defined products structured as an asset or stock purchase of a product-specific Newco
- Facilitates effective liquidation and spin-out of desired asset, with retention of other rights
- Tax-intensive structuring and acquisition consideration
- Examples: Forma/Genentech; Constellation/Genentech; Nimbus

Concluding Remarks

- Understand the market and who is really a potential collaborator/buyer
- Do your homework – understand the partners and have a strategy and goals
- Control and be thoughtful about the process, particularly timing
- Be straightforward about the goals
- Be willing to walk away or choose a different path
- Stay focused on key objectives but watch impact on future deals
- Engineering is fun – but don’t let the “deal” get in the way of the deal
- Don’t overlook complexity or underestimate the costs of your commitments

Questions? Comments?

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