DEAL PREP

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DEAL PREP

- An overview of the process
- Discussions of
  - Negotiations
  - Term sheets
  - License Agreements

PROCESS TO A DEAL

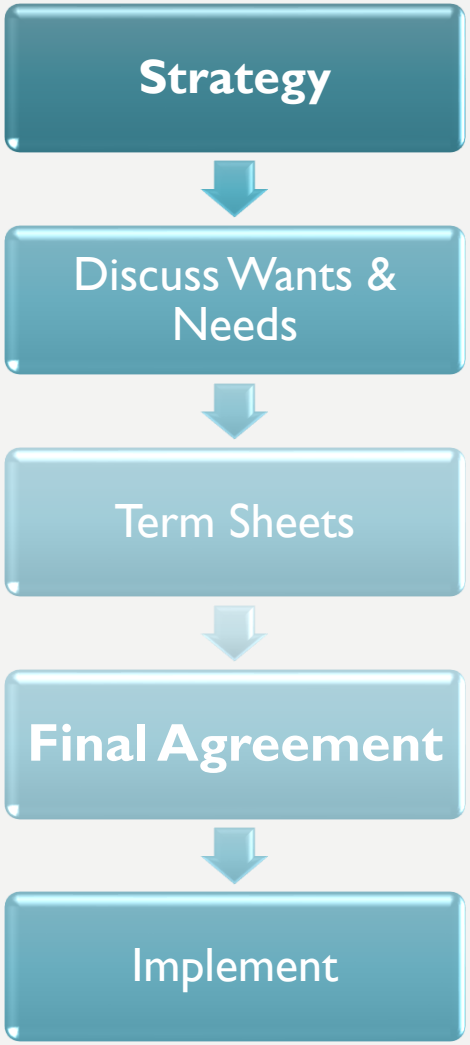
- Partner's triage
  - ~500 opportunities received per TA
  - ~100 non-confidential meetings
  - ~50 CDAs and non-confidential meetings
  - ~20 requests to Sr. Mgmt for diligence
  - ~10 term sheet negotiations
  - ~5 agreement
  - ~4 full deals signed

TYPICAL TIMING FOR A DEAL

- Perhaps a month for a CDA
- A month or more to schedule a confidential team meeting
- A month of review before diligence decision
- ~6-9 months from a Yes decision
  - Diligence
  - Term sheet negotiations
  - Full agreement negotiations (1-2 weeks per turn per side)

NEGOTIATIONS

THE NEGOTIATING PROCESS



PROCESS FOR NEGOTIATIONS

- Typically financials after diligence (but later stage = less diligence upfront)
  - Diligence a big resource commitment for both sides
  - Diligence leads to partner's valuation
  - If term sheet is exchanged before, diligence will probably lead to reductions in terms
- Prior to term sheet, exchange "wants and needs"
  - A conceptual discussion of what is important
  - Lessens risk of "shock" and misfit of term sheet
- Multiple rounds of term sheets
- Drafting of full agreement

NEGOTIATION PREP

- The Inside Battle – get ready to send clear cohesive messages
  - Decide Goals, BATNA, Wants and Needs
  - Profile potential partner
  - Profile your SWOTs for the negotiation
  - Decide on approach

GOAL, BTNA,WANTS AND NEEDS

- What is the goal for the deal? Why are you doing a deal?

BATNA- what is best alternative to a negotiated agreement?

- What will you do if you do not get this deal?
- Hopefully, you have built some alternatives by seeking other partners and having plans for your own development

Wants and Needs ($, Control, Resources, Path to a Future)

- Needs – things you must have to do a deal
- Wants – things you might trade for a need
    - Prioritizing
        - Think about criteria
        - Think about 1:1 swaps and swaps of 2-3 for 1 need or higher wants

Wants and Needs (Interests) not the same as positions

- Positions are the terms you present to them
- Wants and Needs should be more conceptual, with reasons behind them

- SWOT- what are your SWOTs for this negotiation

TYPES OF WANTS & NEEDS

- Money Now or later – need an immediate deal? Want maximal royalties?
- Time / Progress now or later
- Resources - Mine or yours or someone else's
- Avoidance or removal of risk – marketing muscle?
- Options/ Flexibility
- Control
- Image, Validation, Publicity
- Relationships
- Quality
- Message for investors
- Pathway for growth – participation in development, commercialization

EXAMPLE STATEMENTS

- #1 Goal for a deal
  - Cash to run other programs
  - Commercialization power to maximize drug
- Needs that must be met or no deal
  - Partner we can work with
  - US co-promotion rights
- BATNA – best alternative to a deal
  - Run 1 trial and risk all on that
  - Take more dilution from investors
  - Wait 6 months
- Wants – that we may trade away
  - Co-promote we won't actually use
  - Higher royalties vs earlier payments

PROFILE PARTNER

- Understand capabilities
  - Sales
  - Therapeutic area expertise
  - Pipeline
- Understand history of their deals (get deal summaries, contracts)
- SWOT (internal: strengths, weakness; external forces: opportunity, threats)
- Postulate wants and needs and their BATNA and see how they fit with yours

OPEN DISCUSSION

- State your assumptions about the aims of the negotiation
- Start with the big items as concepts – as an exploration
- Start higher than you want to end up but not beyond a reasonable justification
- Frame the positions for persuasion to fit their needs and wants
- Have the next step prepared in case it goes well

TERM SHEETS

TERM SHEETS

- Define the "material terms and conditions of a business relationship"
- Generally non-binding
- "Relatively" short
- Incomplete!
- An **evolving** part of a negotiation
  - More detailed as progress
- Leading to a full agreement

WHO, WHAT, WHEN

- Who?
  - Either side can provide the first term sheet
  - Generally the party with the most concrete ideas writes the terms at each step
  - Authoring can mean greater control and understanding
- What?
  - The most important terms to you
- When?
  - AFTER you have done your prep on goals, BATNA, SWOT
  - AFTER you have some understanding of both sides wants & needs
  - AFTER you know some things about the structure
    - The asset
    - An option, license or purchase
    - What rights (scope, field)
    - Exclusive, non-exclusive
    - Worldwide or limited territory

WHAT IS IN A TERM SHEET?

- Must include:
  - Names of the parties
  - Description of the asset
  - Type of deal (license, option, purchase, investment, JV…)
  - Binding or non-binding
    - Binding very rare as it will serve as the full agreement if disputes prevent a more complete agreement
- Can include:
  - A purpose
  - Financial terms or placeholders
  - Governance (decision making)
  - Diligence for licensor's development of asset
  - Dispute resolution
  - Termination clauses

LICENSING AGREEMENTS

DEFINITIONS

- Often critical to understand the agreement
- Should be interpretable to those outside the agreement

SCOPE

- Granted a license or option to….
  - "Research, Develop, Make, use, sell, offer to sell"
  - Licensed products, Patents and patent applications (all or listed?, CIPs, divisions, extensions), specific compound, backups?
    - All owned and controlled or listed patents and applications
    - Or only that necessary to make, use, sell Licensed Product
    - Derivatives a tough to define area
  - Exclusive or non-exclusive
    - What rights does the licensor retain? Research? Royalty free typically
  - Territories - consider gray market imports
  - Field of Use
- Does the license extend to affiliates, wholly owned subsidiaries or subcontractors? Can it be assigned?
- What happens in a change of control? In the event of bankruptcy?
- Includes improvements? Non-exclusively? With a time limit on which improvements?
- Including know-how? (and how is that transferred)

FIELD OF USE

- Tends to be broad in discovery and narrower as get to market
  - All uses
  - Human therapeutic and prophylactic
  - Diagnostic
  - Animal use
  - Including or Excluding specific indications
  - Including or Excluding route of delivery (oral, topical, inhaled…)
  - Including or Excluding types of molecules (proteins, antibodies, gene therapy, conjugates, fragments….)

SPLIT INDICATIONS – USUALLY ONLY WITH A SEPARATE FORMULATION OR DOSAGE!

- Off label use can lead to disputed sales
  - Sales are tracked by dosage form (sku)
- Amgen- Ortho (J&J) EPO deal
  - Amgen's Field of Use is to treat kidney dialysis patients in the US
  - Ortho has EPO ex-Japan and ex-China, and ex-Amgen's Field of US
  - *In June 1991, after arbitration, Ortho was awarded $164 million associated with Amgen's failure to assist Ortho in the timely approval of Procrit, plus ex-kidney dialysis sales*
- Schering Plough – Cephalon Remicade deal
  - If the Product Committee cannot agree as to whether or not the Product should be developed for a New Indication, one party may independently proceed; provided, however:
  - the non-developing party may rejoin at the completion of the first Phase IIb trial by repaying __% of costs;
  - the New Indication must have a different formulation or different dosage form; and
  - the New Indication must be sold under a separate and distinct trademark.

TERRITORIAL SPLITS- INFO SHARE

Concerns about coordinating development and marketing to avoid conflicts; clinical trials in each other's territories, avoid obligations for possible additional partners after sublicensing.

Reports and Joint Committees

- Party1 shall provide Party2 with
  - (i) all data and results of toxicological or other **animal studies** of Product conducted by or on behalf of Party1 or its Affiliates or Sublicensees within fifteen (15) days after receipt, and in the event any animal dies or develops a clinically significant **adverse event** or any other finding is made that suggests a significant risk for human subjects, Party1 shall fully investigate, and use reasonable best efforts to determine, the cause of death or other abnormalities, and report all findings in writing in no less than five (5) days after such findings are made and
  - (ii) **a final report for each clinical study of Product** as soon as practicable after completion of the study and the analysis of the results, but in any event within fifteen (15) days after such report has been prepared by Party1
- Party 1and its Affiliates and Sublicensees shall provide
  - copies of the applicable **protocol for each human or animal study** of Product, including any pharmacological, pharmacokinetic and toxicological studies, at least thirty (30) days prior to initiation of the study, as well as any proposed amendments thereto at least fifteen (15) days prior to implementation thereof, and consider in good faith any comments provided by Party2.
  - copies of **all premarket approval applications** (PMAs), premarket notifications (501(k)s), new drug applications (NDAs), investigative device exemption applications (IDEs), investigational new drug applications (INDs) or comparable U.S. or foreign regulatory filings with respect to Product, all correspondence with regulatory authorities with respect to Product and all annual reports submitted to regulatory authorities with respect to Product.

TERRITORIAL SPLITS – AE AND PHARMACOVIGILANCE

- Requirements for Adverse Event reporting and a separate Pharmacovigilance Agreement
  - Product Safety Reporting. Party 1 shall be required to report to Party 2 in writing all Serious Adverse Events from clinical trials of Product sponsored by Party 1 or its Affiliates or Sublicensees. Party 2 shall be required to report to Party 1 in writing all Serious Adverse Events from clinical trials of X, but only to the extent such serious adverse events are reportable to the FDA pursuant to 21 C.F.R. 312.32(c)(1)(A) or successor regulation. The parties shall exchange such adverse experience reports in a manner and time frame that will allow compliance with regulatory reporting requirements, including any requirements of the United States Food, Drug and Cosmetic Act and regulations promulgated thereunder and, if applicable, guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.
  - The parties will enter into a **Pharmacovigilance Agreement** with respect to standard operating procedures for reporting these events to each other prior to Party 1's initiation of any clinical studies of Product.

COMPENSATION

- Upfronts
  - Non-refundable
- [Equity and its terms]
- Milestones – regulatory and sales milestones
  - Want clear definitions of events
  - Typically on "successful" completion or start of next phase
  - Paid one-time, per indication, per molecule (backup)
- Royalties
- Profit share
- Sublicensing share?
- Payment for development, regulatory filings
- Quid or other form of value including data use

ROYALTIES

- On net sales
  - Combination products with a formula for relative contribution
  - Often tiered on sales (generally up with increased sales)
- Definition of net sales can make a difference (5-9%)
  - Exclusion may include, (1) import, export, excise and sales taxes, and custom duties; (2) costs of insurance, packing, and transportation from the place of manufacture to the customer's premises or point of installation; (3) costs of installationa t the place of the use; and (4) credit for returns, allowances, or trades.
  - Typically with right to audit and penalty for missing
- For a term of x years or last to expire valid claim or for as long as sold (less common)
- Reduced or eliminated if
  - "Reduced by 50% if …"
  - 3rd party IP use or required
  - If 3rd party royalties are paid (often with a threshold)
  - No valid claim (on country by country basis)
  - Introduction of a market competitor (with a % sales on unit or dollar terms)
  - Change in reimbursement status (stepped)
  - Never to be less than x% (floor)

MANUFACTURING AGREEMENTS

- Generally a separate agreement for a company to supply another
- Topics include:
  - Transfer price or cost plus
  - Performance metrics
  - Second source
  - Incentives for process improvements
  - Technology transfer and its support

NON-COMPETE PROVISIONS

- One-way or reciprocal, Specific diseases, Types of molecules, targets
- Examples
  - Licensor will not develop, partner or sell the same compound and/or in the Field
  - Licensor will not develop, partner or sell Competing Product (same MOA) in the Field for 5 years
  - If Licensor develops, partners or sells same chemical structure outside Field, ensure formulation prevents substitution and development program differs in other respects
  - Both parties will develop and market products separately and may become competitors
  - Neither party will develop or partner Products in the Field and Territory except through this alliance
  - Neither party will develop or sell any Competing Product –divest or terminate. Compound for use outside Field must have different (a) dosage strength, (b) formulation, or (c) delivery system
  - If Licensee sells Competing Product in Territory, negotiate either (i) co-promotion by Licensor or (ii) adjustment in gross profit split. If neither, then Licensor may terminate agreement
  - If Licensee sells Competing Product, then Licensor may elect (i) minimum royalties at 80% of forecasted sales for 3 yrs or (ii) repurchase rights for 0.5x to 1.5x sales for preceding year (depending on patent life)

SUBLICENSING

- Why?
  - Pharma wants ability to sublicense for territories (development and/or marketing)
  - Often a mid-size company wants ability to sublicense at POC or beyond
- Limitations
  - Limit on numbers and levels
  - With permission, not to be unreasonably withheld? Rare
  - Notice
  - Pass thru obligations or With the same obligations or no less stringent
- Share in revenues beyond terms of first license
  - % of upfront or all cash except R&D support
    - Often tiered to be less with time (reward if flipped)

INFORMATION SHARING AND PUBLICATIONS

- Can the Biotech benefit from the data being developed?
  - In the event of termination?
  - In the event of Biotech sublicensing its retained rights?
- Biotech often wants a deal announcement
  - Who issues? Who approves?
- Publication rights?
  - Who publishes? Who reviews? Only to remove confidential material?

IP

- Who owns, prosecutes, defends and pays for IP
- Who owns, prosecutes, defends, and pays for IP on improvements
- What happens if a patent application never gets issued?
- What happens to the terms when the patent expires?

CONTROL AND RESPONSIBILITIES

- How are we to work together?
- Who decides and who does what?
  - Big divisions of labor (ie, you manufacture, we sell)
    - By expertise or capabilities
  - Division by indication or formulation
  - Decision by committee
  - And combinations thereof
- Protocol review
- Veto on studies reasonably deemed to risk damage

CO-PROMOTION

- In about 25% of all deals, more common in later stage and big deals
- Generally go along with co-development role
- Usually for limited territory, indications
- Can be number or % of reps, details, or medical liaisons
- Predefined or decided by committee
- Divided by indication, specialist, institution type (hospital, managed care)
- Exercised upon start of NDA enabling trial, filing, launch
- For the life of the product or a limited term
- Licensor paid by royalty upstep or by per detail or by profit split
- Co-promotion may be lost by change of control
- Control on training and promotional materials

DILIGENCE REQUIREMENTS

- Purpose = to ensure get back-ended value
- Ideally, should be clear, objective, and reportable
- Best efforts (rare)
  - Requires use of its highest efforts to perform its obligations and to maximize the benefits to be received by the other party, although it does not generally require the party to achieve any specific goals.
  - Comparable to the efforts used for its own products
- Specific goals
  - Timetable for development stages (rare)
  - Meet with payment of milestone or Buy extensions?
- Minimum annual spend
- Minimum annual royalties
- Commercially reasonable
  - Less stringent than that imposed by the 'best efforts' clauses.
  - a subjective test of what a reasonable person would do in the individual circumstance, taking all factors into account. A standard of reasonableness defined by what a similar person would do as judged by the standards of the applicable business community.
  - A business may give reasonable consideration to its own interests, exercising discretion within its good faith business, judgment, in devising a strategy for achieving its ultimate goal.
- How do you know if it is being met?
  - Annual or semi-annual reporting of plans and progress
  - Seat on committees

TERMINATION PROVISIONS

- Who can terminate?
- When can they terminate?
  - At will, after a certain Time, breach, bankruptcy, change of control
- What happens on termination?
  - For each right granted, what is returned
  - What rights and obligations survive (usually confidentiality and payments previously obligated)
  - Steps necessary for an orderly transition
    - Sell remaining stock of product inventory(and pay royalties)
    - Manufacture for some defined time period
    - Transfer of manufacturing technology
    - Transfer of improvements (rights and obligations)