Business Development Basics Course

Sourcing and Implementing the Deal: Key Take Away Points

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Course Agenda

- Due Diligence
- The Role of Alliance Management
- The Importance of Marketing In Licensing
- Non-Confidential versus Confidential Packages
- Term Sheet and Definitive Agreements
- Resources for the Licensing Professional

Due Diligence

Due Diligence Begins with Evaluating Non-Confidential Information

- Annual Reports
- Analyst, Industry or Trade Reports
- Press Releases
- SEC Filings
- Investor Conferences
- Healthcare Meetings
- Personal/Professional Contacts
- Board Membership – Directors and Advisory

Initiating a Confidential Disclosure Agreement (CDA) Begins the Formal Process

- Scope
- One-way vs. two way
- Duration of terms
- Restriction of circulation of material for review
- Standstill provisions
- Poaching practices
- Closure post due diligence

Pharmaceutical Due Diligence Teams Must Obtain and Review Source Documentation

- Scientific rationale
- Preclinical safety
- Chemical and pharmaceutical development
- Drug metabolism and pharmacokinetics
- Clinical safety and efficacy
  - Special populations
  - Organ dysfunction
- Regulatory filing status
- Patent status
- Third party contracts

Target Product Profile Required for Guidance

- Indication(s)
- Route(s) of administration
  - Dosage form(s)
  - Storage
- Outcomes or endpoints to be achieved
- Short and long term side effects and toxicities
- Comparative data
  - More effective than…
  - Safer than…
- Life cycle considerations

Alliance Management

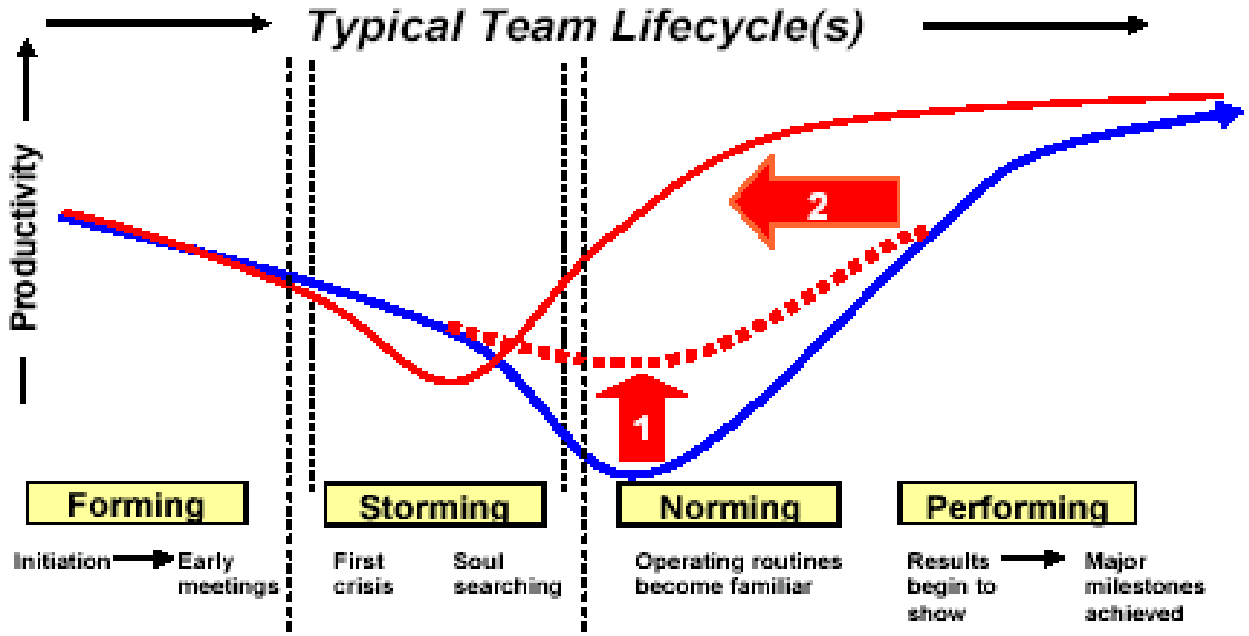
Preventable Failure of Alliances

- Poor communication accounts for 57%* of deal failures
- Other major reasons for alliance failures include*:
  - Poorly negotiated Terms
  - Poorly Defined partner roles
  - Ineffective Leadership
  - Weak Internal and external commitment
  - Cultural differences
- These failures are preventable – they can (and should) be avoided with effective Alliance Management

***Cutting Edge – Pharmaceutical Alliances Licensing and Deal-Making Survey**

Effective Implementation Improves Alliance Productivity and Success

Goal: Improve the probability and speed of alliance success



Foundational Fundamentals

Leadership, Trust, Communication, Governance

Implementation Plan

- **Responsibility:**
  - Alliance leader(s) (plus PJM leader)
- **Timing:**
  - As early as possible: during early development of negotiated agreement?
- **Key Success Factors:**
  - Management support for resources (FTE, $) required as part of final DRC deal sign-off
  - Experienced personnel in key leadership functions
  - Governance structure fully staffed on signing

Key Success Factors – Pre-Signing

- Assign personnel to the alliance
- Explicitly understand each partner's business strategy and how each can add value to the alliance
- Analyze both companies cultures/operating norms for synergies and potential conflicts
- Have agreed and functional alliance governance framework with potential partner
- Develop 1 year work plan and budget with key emphasis on 90 & 180 day targets / deliverables

Key Success Factors – Immediately Post-Signing

- Train internal teams on alliance effectiveness (dos and don’ts)
- Implement Kick-Off meeting
- Ensure teams share understanding of Alliance’s strategic intent, contractual obligations, governance operating principles, communication and conflict management
- Begin appropriate data transfer
- Develop common set of transparent financials
- Review and implement **90** & **180** day Alliance Action Plan
- Monitor baseline and assess progress/health of alliance

If There Isn't a Market, What Is There?

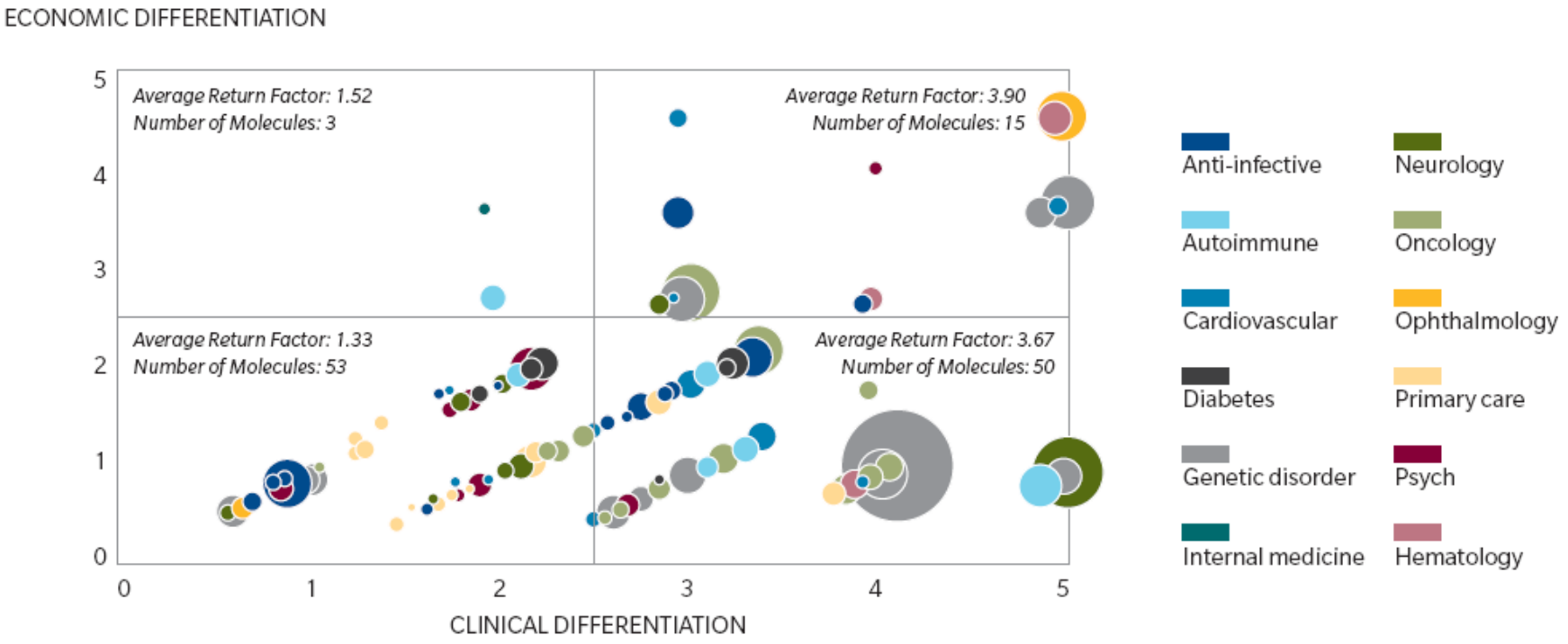
Desirable Characteristics

- Strategic fit
- Market size
- Novelty
  - First or second in class is ideal
  - Strong IP (Composition of matter and methods)
    - Freedom to operate
- Validated mechanism of action
- A clear regulatory and clinical path
- Reimbursable

To be successful a technology must differentiate itself from other competitive products and be positioned in such a way that carves out a market niche.

The Most Clinically Differentiated Drugs Have Greatest ROI

This chart plots all FDA-approved new drugs from 2005 to 2010 according to how differentiated they are from other drugs in the space clinically (X axis) and economically (Y axis). The size of the plot reflects the economic performance of the drug relative to development costs. A key observation: The most clinically differentiated drugs produced the greatest returns.



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METRIC	1	2	3	4	5
CLINICAL DIFFERENTIATION	Efficacy and safety profile is considered to be undifferentiated from any currently approved therapeutics	Efficacy and safety profile is considered to be differentiated only in certain patient sub-populations; significant disadvantages versus standard of care may exist	Efficacy and safety profile offers some advantages over existing therapeutics for use in a broad patient population but is considered inferior to first-line standard of care	Efficacy and safety profile offers strong advantages over one or more classes of existing therapeutics and is considered to be non-inferior to first-line standard of care—a potential first line alternative	Efficacy and safety profile is considered to be breakthrough; a new first-line standard of care
ECONOMIC DIFFERENTIATION	No economic evidence could be found from manufacturer; economic differentiation not a priority	Product offers a weak health economic model; assumptions are challenged by review agencies like NICE for lack of robustness	Product offers adequate health economic model, demonstrating some elements of value versus other branded agents; review agencies provide conditional endorsement based on significant price discounting scheme and/or use after less expensive agents	Product offers robust health economic model showing significant value-add versus other drug therapies based on validated clinical data; review agencies provide unconditional endorsement	Product demonstrates significant total cost-of-care reduction (e.g., lower rates of hospitalization, emergency department visits, and other medical expense). Health economic value-add is unequivocal and review agency endorsement is unanimous

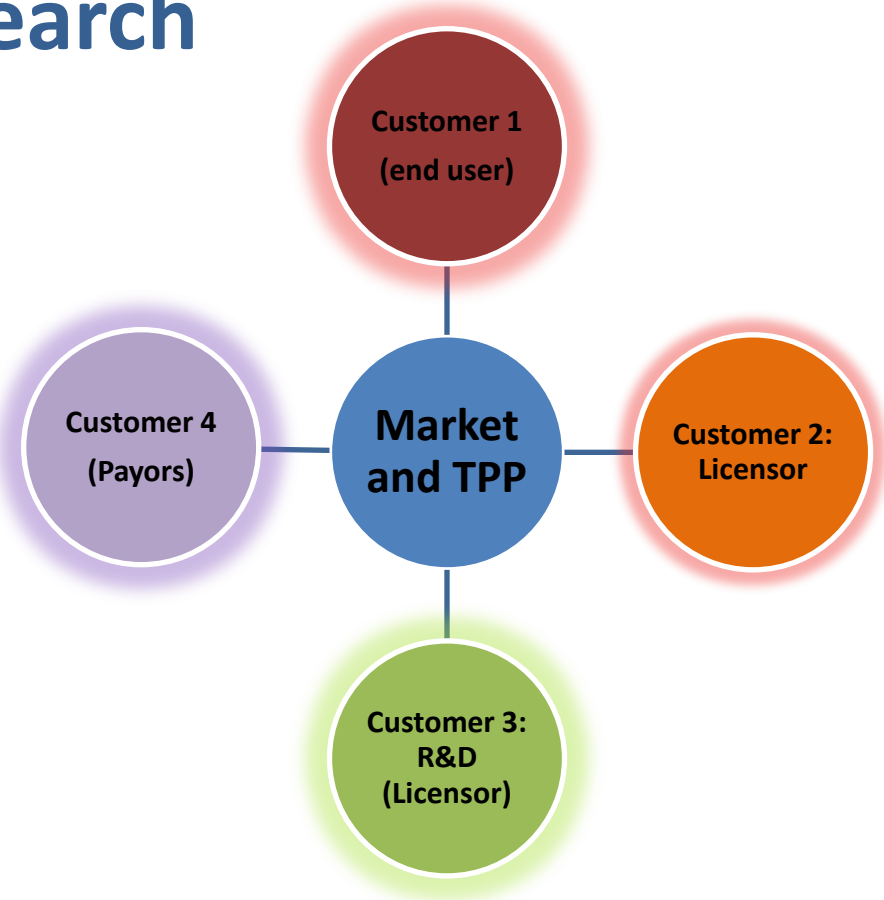
Differentiation vs. Positioning

- Differentiation is what a company does to develop the product to allow it to sell and compete in the market → TPP (target product profile)
- Positioning or a positioning statement is what a company does to *create a perception* about that product or the company. Positioning is a battle for your mind. It is not a tagline.

How Well Do You Really Understand the Market and Your Product?

Rationale for Conducting Primary and Secondary Market Research

- Understand the needs of the customer
- Understand the competitive market
- Provide input for clinical and regulatory path
- Validate differentiable attributes and enables you to position it with greater strength.
- Provide inputs to develop your forecast (bottom - up method.)
- Helps the partner better understand the potential for how the product will be used and reimbursed.
- Provides and a measure of validity and credibility to your story.



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Creating A Compelling Licensing Story

What Problem Is Your Technology Trying To Solve?

- What is the market need?
- Why does this problem exist?
- Why has no one solved this before?
- What barriers exist?

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How Does Your Technology Provide a Solution?

- How are you solving the stated problem?
- What is unique about your technology versus your competition?
- How does the technology work?
  - State the take away message of the data as the title
  - Use visuals/charts to summarize the data

What Are The Differential Characteristics of Your Technology?

- How do you show your technology is an improvement over anything else? How will you position it?
  - Is your IP defensible?
  - How will it be used?
  - Is it first in class?
  - Demonstrable efficacy versus other standards of care?
  - Enables speed of development/ speed to market?
  - Easier to give/reduced dosing frequency?
  - Economic advantages?

→ ***Remember to translate features to benefits***

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Who Is Your Customer and What Is Your Market?

- Who/what is the customer base? What will influence them to adopt?
- How big is the market? Room for expanded indications? Can you realistically quantify it? Have you done a bottoms up forecast? What/who are your sources?

What Milestones Have You Achieved and What Is Your Plan?

- What have you achieved to date?
- What do you want to do next?
- What are you looking for in a partner? (Not necessary to go into detail about terms.)
- Why do you want to partner with them?

Who Are You?

- List team members – keep it brief
- Highlight successful financing or key successes
- Think about how a licensing relationship will fill talent gaps

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Non Confidential Presentations

- Know your audience and tailor the document.
- State in the document it is non-confidential and be sure to *make sure your team understands it is non confidential*.
- Do not include P&L, cash flow or other financial statements.
- Try to limit your presentation to no more than 15 slides if possible
- Use PDFs.
- Hard copy: adopt the same story, but keep it to no more than two pages.

Confidential Presentations

- Do not submit as a first pass unless there is no option.
- Need a signed CDA.
- Make sure materials to be distributed are clearly labeled confidential.
- Know your audience (who, titles, etc.)
- Be prepared to discuss more detailed information about
  - Preclinical, clinical date.
  - Patent estate (note: this is not a freedom to operate exercise)
- Remember this is not due diligence.

Avoid LOUD fonts, vibrating colors and use of shadows.
Make sure it looks professional!

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"I do. Have your people contact my people to hammer out the details."

TERM SHEETS and DEFINITIVE AGREEMENTS

ACTIVITY DESCRIPTORS

- Why?
- Who?
- What?
- How much?
- Where?
- How?
- When?
- For how long?
- How well?

CORE ELEMENTS

- Field
- Licensed Product
- Territory
- "Exclusivity"
- Sublicense provision
- Definitions

ACTIVITIES

- Various Payments
- Project Governance
- Creation of new IP
- Who will do the work
  - Research
  - Preclinical Development
  - Clinical Development
  - Regulatory
  - Manufacturing
  - Marketing
  - Sales
- Work plans
- Prosecution, maintenance and litigation of IP
- Indemnification
- Representations and warranties
- Term and Termination

Please refer to accompanying term sheet example in your binder.

Common Transaction Mistakes

- Expectations between parties are not clearly understood.
- Lack of cohesiveness between your board and management.
- Lack of team input.
- A “just get it done” mentality.
- Saving difficult issues for last.
- Wordiness
- Skipping the term sheet altogether
- Undervaluation
  - Payments for each Licensed Product
  - For additional Indications of the Licensed Product
  - For activities associated with each Licensed Product and extensions of such activities if needed

Sourcing Partners and Networking

- Build a “rolodex” and leverage your contacts.
- Know your partner, know yourself
  - Management team
  - Partnering portal
  - Drugs in development
  - Recent deals/news
- Leverage your colleagues, board of director and investor contacts.
- Follow trade publications

LinkedIn

The New Rolodex???

Resources For The Licensing Professional

FREE

- Yahoo finance (biotech, pharma, devices, diagnostics, manufacturing)
- Xconomy
- OnBioVC
- Fierce Biotech/Pharma
- BIO SmartBrief
- Elsevier Weekly Transactions
- Current Partnering
- SEC documents
- RSS feeds
- VC web sites

SUBSCRIPTION/FEE FOR SERVICE

- Databases
  - RECAP (Deloitte)
  - Strategic Alliances (Windhover/Elsevier)
  - ADIS R&D
  - Hoovers
  - Pharmaprojects
  - IdDb3
  - ThomsonPharma
  - MedTrack
  - Venture Source (Dow Jones)
- Publications: In Vivo/Start – Up. BioWorld, BioCentury, DIA newsletter, Pink Sheet
- Secondary market research reports

http://www.vstratadvisors.com/#!resources

Questions? Suggestions?

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