



“Preparing Your Company For Corporate Partnering”

Discussion Materials

August 2012

The Three Implicit Goals at the Core of All Corporate Partnering Deals

1. The creation of shareholder value on both sides of the transaction;
2. The delivery of therapeutic/diagnostic benefit (hopefully in areas of unmet medical need); and ultimately
3. A healthy commercial return

**[Assume “Pharma” is the party obtaining X
Assume “Biotech” is the party providing X
And X = therapeutic, medical device, diagnostic, tool and/or technology]**

Adapted from: Datamonitor – Pharmaceutical Licensing Overview; Risk-aversion breeds creativity as externalization intensifies, March 2010

The Provocative Tripartite Question

- Is Pharma company licensing-in innovative products and technology from Biotech to its advantage

Or

- Is a Biotech company contracting in services like clinical development (clin dev), regulatory expertise, sales & marketing and manufacturing to its advantage

Or

- Does the truth lie somewhere in-between and is it the result of careful analysis and subsequent negotiation?

Agenda

1. Background to Corporate Partnering Exercise
2. Preparing Internal Culture
3. Finding and Dealing with Possible Partners

Multiple Objectives Of Any Externalization Strategy

- Larger size
- Filling in product or technology gaps, protecting the therapeutic/diagnostic franchise
- Geographic complementarity
- Expertise (R&D, clin dev, regulatory, manufacturing, sales)
- Greater financial stability
- Better image to shareholders, counterparties, external collaborators
- Cash generation – short term and long term

What Is The Difference Between Corporate Partnering and Similar External Strategies?

- Marketing Agreements – involves the granting of rights to create/sell a given product or technology in an identified territory
- Licensing Arrangement/Product Acquisition – similar to a Marketing Agreement, but there is a greater level of corporate commitment and resources; as a licensing agreement = a long term lease and a product acquisition = up-front lease + a full-payout
- Outright Acquisition – an all encompassing transaction where the entire company is purchased (including plant R&D, sales of the existing product(s), IP etc...)
- Joint Venture – the creation of a new and free-standing enterprise, usually occurring when two parties with complementary IP/technology (or market coverage or product ranges) decide to pool resources so as to achieve benefits of scale ($2 + 2 = 5$) and resultant profitability
- Corporate Partnering (CP) – where a Pharma company, with full manufacturing and sales capabilities, extends its operating, financial and product development assistance to a smaller, underfunded, but highly creative, Biotech company which has an "idea"

A Corporate Partnering Deal

A CP Looks Like A Giant Club Sandwich

- Upfront license/technology access fee
- R&D support funding at regular intervals
- Milestone payments (for patent, scientific, clinical, regulatory and/or commercial achievements)
- Royalties
- Manufacturing/supply of the product/active key ingredient
- Equity (as “spice” sometimes)

What Are The Interlocking Goals Of Corporate Partnering?

“Pharma companies are relying less on in-house R&D operations and turning toward building up in-licensed drug discovery technologies and drug development projects. With such operations becoming increasingly important, corporate partnering activity has become a priority for drug makers in boosting corporate value¹”

Biotech

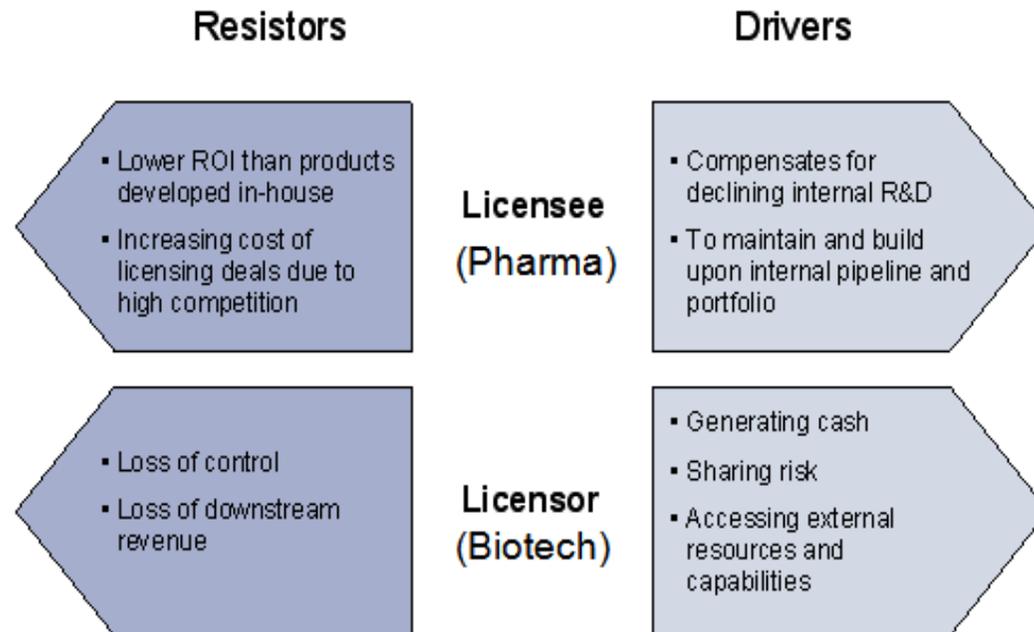
- Get cash to survive and thrive
 - Access to :
 - Markets/ commercial muscle
 - Expertises
 - manufacturing base
 - Validation of technology to private investors and public stock markets
- (All done without necessarily selling more equity)

Pharma

- Buy R&D less costly and more rapidly (\$500M and ten years) than in-house work to fill a product or market gap
 - Use existing, costly infrastructure in manufacturing, sales/marketing, regulatory affairs and clin dev
 - Access to innovation in technology or products
- (All done without an acquisition of an outside company)

Source: ¹Daiwa Capital Markets Research Update, Pharmaceutical Sector: Near Term: New Drug Launches; Mid-to-long Term: in-licensing, M&As, emerging markets, 03/04/11

Key Drivers and Resistors Facing Licensees and Licensors in Today's Pharmaceutical Industry



Note: ROI = return on investment

Source: Datamonitor – Pharmaceutical Licensing Overview; Risk-aversion breeds creativity as externalization intensifies, March 2010

Other Managerial Motives for CP

- Resource focus = maintain your best core competency, outsource the rest
- Share risks = get the other guy to put up cash or specialist skills on a project whose dimension or uncertainty is too much for your company
- Flexibility in managing it = there is informality, greater ease of co-opting key people..... at least for a while
- As a reaction to climate change within the pharmaceutical industry (increased genericization, pricing and reimbursement, regulatory issues and higher costs of R&D)²
- Style = no longer just the classic choice of “Buy or Build”, now you can “Bond” (= “Rent”)

Source: ²Datamonitor – Pharmaceutical Licensing Overview; Risk-aversion breeds creativity as externalization intensifies, March 2010

When Not To Pursue A Corporate Partnership

- Imperative need to build up requisite business skills in-house, such as marketing/sales force or regulatory affairs expertise
- Reasoned fear of runaway technology
- Concern over early termination of the R&D element of, or risky funding for, the collaboration

Two Crucial Management Steps For Success in CP

- Preparing your company and its internal corporate culture to do Corporate Partnering
- Selecting, and making contact with, appropriate potential partners

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Self-assessment Elements at a Company Wanting to do a CP

- Personnel and Processes
- Finances
- Operating Elements
- Science and IP Position
- Public and Market Reception
- Creating a Supportive Atmosphere

Self-assessment Elements - Personnel And Processes

- Leadership of Corporate Partnering program (R&D, business, strategy, finance, internal reputation)
- Availability, competences of key people
- How secure/confidential is the internal information sharing process amongst staff
- How broad/deep are business and R&D teams: has anyone prior experience in CP
- For the Biotech, are lab notebooks and clin dev records readable?
- For the Pharma, will your reviewers – at the initial screening – have open minds not clouded by the selfish “NIH disease”

Self-assessment Elements - Finances

- What is the Biotech's current cash position relative to its near term burn-rate?
- What is the Pharma's cash position and expected cash flow over the life of the partnership
- Can the Biotech raise cash from current or imminent investors to supplement Corporate Partnering cash?

Self-assessment Elements - Operating Elements

- For the Pharma, it should determine whether its own products are positioned as leaders or followers in their franchise field(s) and whether Biotech's X will be additive (and the converse analysis for Biotech)
- For the Pharma, how effective is its sales force now and can it handle the new X
- For the Pharma, can its manufacturing facilities (if any) support the combined growth plans
- For the Biotech, is the production process so complex or proprietary that it must be done in house by the Biotech? Or can it be transferred to the Pharma (as part of the deal? or as an "extra"?)
- How long will it be to a product launch? With what major clin dev, CMC and regulatory risks?

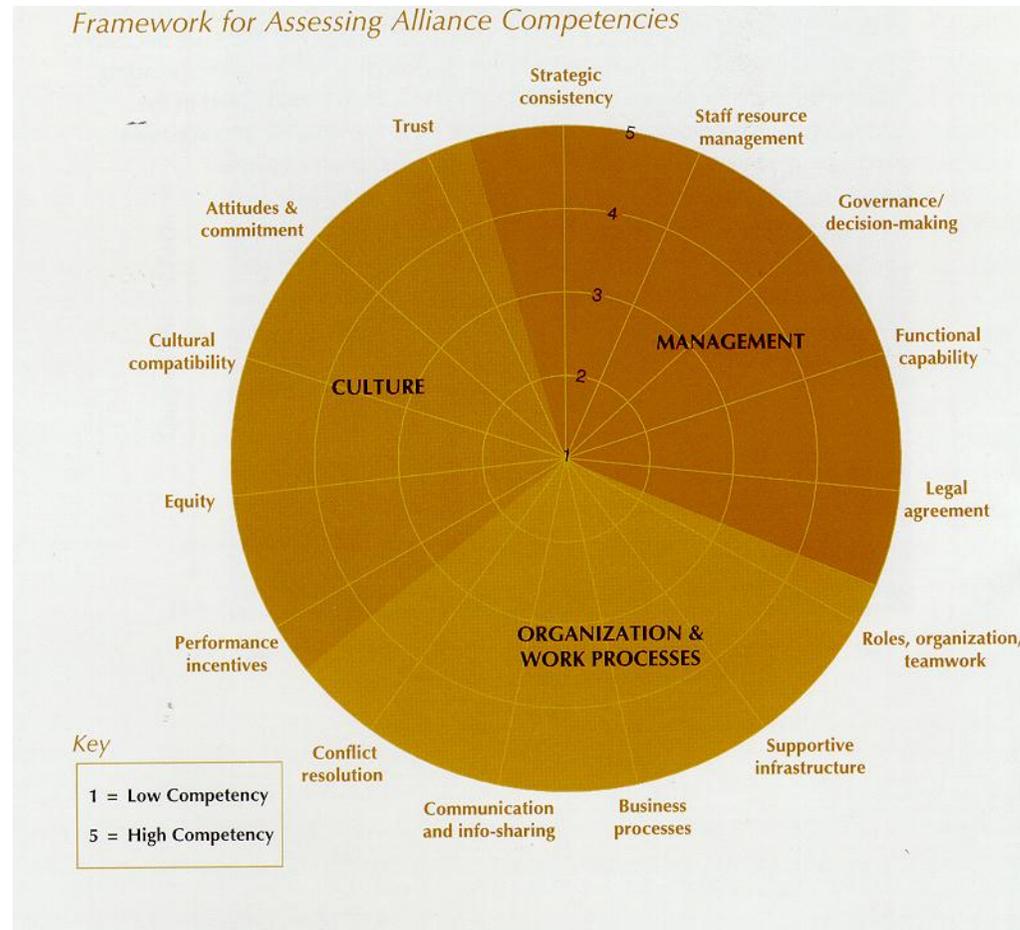
Self-assessment Elements - Science And IP Position

- For the Biotech and for the Pharma, how good indeed is the science and clinical development?
- How defensible are the Biotech's patents?
- How much is being spent.....and how much more needs to be spent for the Biotech to stay “excellent and unique” as well as “ahead”?

Self-assessment Elements - Public And Market Reception

- Will either the Biotech or the Pharma be seen as acting from strength or from desperation in doing a deal?
- How will a Corporate Partnering deal be perceived in the minds of equity research analysts and their investor clients.....or private investors?
- What will the trade press say? The general press?

Framework for Assessing Alliance Competencies



Source : PwC: High-Performing Strategic Alliances

Creating A Supportive Atmosphere

- For the Biotech, make sure the various teams, especially R&D and Clin dev, see the necessity of doing a deal (i.e. understand the benefits to the Biotech)
- Similarly, the Pharma teams should feel privileged to review/analyze/conduct negotiations and to take part in an excellent outside opportunity and not feel demeaned or threatened
- Both parties need to create a “selection committee” to screen partners
- Regular communications about the company’s goals and about the rationale for Corporate Partnering deals to align internal attitudes with outside reality

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Dealing With The External World

A Biotech should choose its Pharma partner based on:

FIT, FIT and FIT,
with a nod to
GEOGRAPHIC FOCUS,
MONEY, STYLE & ROLE
plus
TIMING

Picking The Partner - Fit 1 (for a Biotech Therapeutic Company)

- by therapeutic category (like oncology)
- by indication (like asthma)
- by mechanism of action (like inhibition of the complement cascade in the immune system)
- by sales force / target audience (like specialists, general practitioners, or hospitals)
- by time availability (such as approved, but not yet launched or Phase III etc...)

Picking The Partner – Fit 2 (Context “Need”)

It is best if Biotech's Product (or Compound or Technology) fills a hole caused by:

- Pharma's RX drug is going generic
- Pharma manufactures a me-too RX drug not faring well in the marketplace
- Pharma's RX drug is ineffective, or just partially effective
- Pharma has inadequate/no therapeutic drug in this franchise area
- Pharma has insufficient/no presence in the market

Picking The Partner - Internal Style of That Organization

- At the Pharma, who makes decisions (on R&D, marketing etc...) and how long does it take
- Is the Partner company science-based (like Pfizer) or marketing-driven (like Forest)
- How open is the Partner's culture to new ideas or is it still "N" "I" "H" infected?
- Who is the internal "champion" at the Pharma and what is his/her standing (i.e. power base)
- Is the Pharma treating your situation as a "defensive" or "offensive" transaction
- How "easy" are (and will be) the inter-personal relationships of scientists, clinicians and business people at the Pharma and projected with the Biotech company

Picking The Partner - External Role (of the Pharma)

What does the Biotech need/want from the Pharma Partner? The choosing of these deal “benefits” is everything:

- Just shovel money in your direction
- Add pre-clinical (PK, PD, tox) expertise
- Add clinical development/trials experience
- Do the regulatory filings
- Manufacture the product
- Sell the product (worldwide or regionally?)

.....Maybe buy the Biotech outright or later...

Picking The Partner - Geographic Focus of the Alliance

There are varying appetites from Pharma for territory coverage – and these must match the needs of Biotech:

- Global Big Pharma – the world
- Big Euro Pharma – all Europe plus, nearby nations
- Medium Euro Pharma – most Europe and nearby (export) market
- Regional Pharma – US only, China, India, Japan, Australia and New Zealand

...does Biotech keep back co-development, co-promotion, co-marketing or full rights in one or more territories?

Picking The Partner – Timing of a CP Deal

The Biotech usually wants to partner at proof-of-principle (still pre-clinical) or Phase I

Vs.

The Pharma wants proof-of-efficacy as shown in Phase II or later, not just *in vitro* biological activity
(pre-clinical research) plus safety (Phase I)

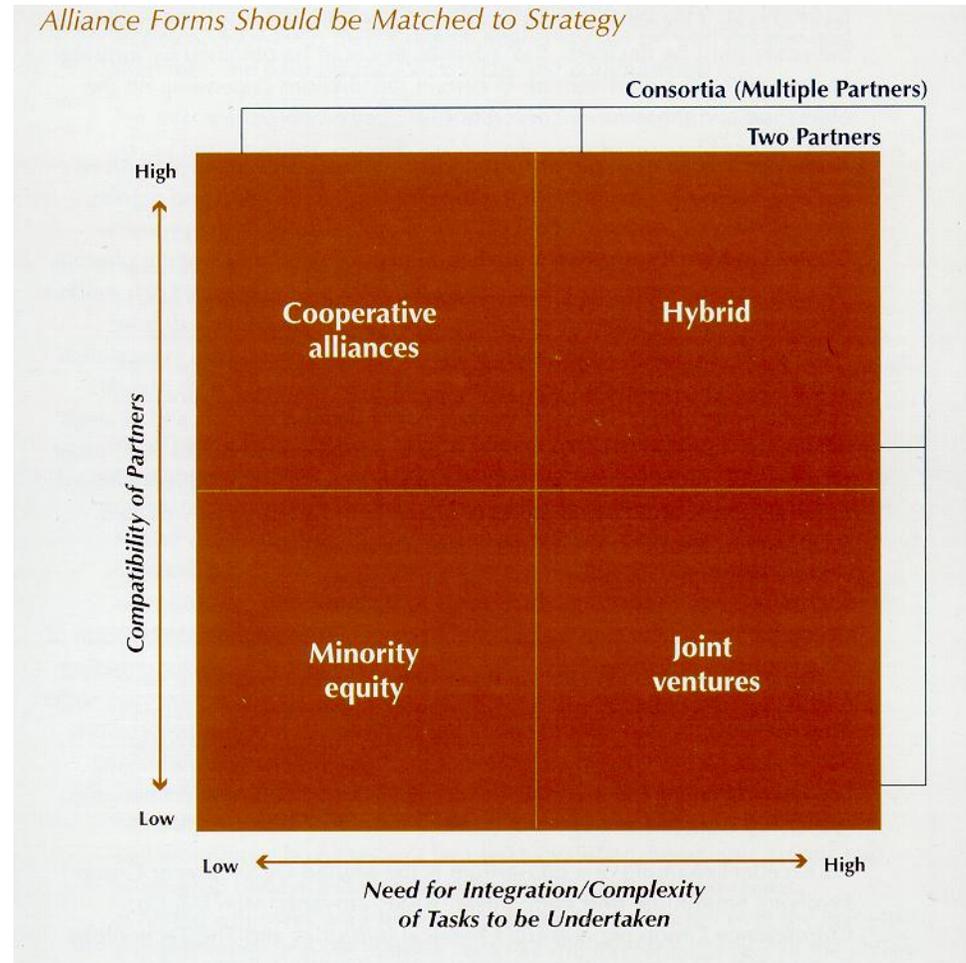
This aspect of a CP deal is always in conflict unless the Biotech is well endowed with cash – and thus impacts many elements of value

Picking The Partner - Money

The more cash in Pharma's treasury, the better, but a deal will be influenced by:

- The status of Partner's franchise
- R&D efforts – human/financial resource commitments
- The cash goals at the Biotech
- Overall deal cost (start to finish)

Various Alliance Forms Underpin a CP Deal



Source : PwC: High-Performing Strategic Alliances

At the Biotech, Who Contacts The Potential External Partners?

- Biotech's scientists or senior management who know their counterparts at Pharma
- Corporate development/business development team at the Biotech company
- Outside CP advisors like Ferghana Partners

How Is The Initial Contact Made by the Biotech?

- Compile a list of contacts at appropriate Pharma Companies
- Speak to management, R&D, business people at Pharma, in parallel
- Create a tightly structured, non-confidential briefing document
- Prepare the Confidential Disclosure Agreement (CDA)
- Prepare a cover letter to Pharma counterparties to highlight technology/products/programs, along with non-confidential materials
- Initiate calls to the selected Pharma companies/key persons to ascertain interest
- Send customised cover letters to those persons, with non-confidential briefing package
- After execution of CDA, allow electronic dataroom entry, send out any remaining confidential scientific information or, better still, arrange confidential presentations by Biotech to Pharma

Who Manages the CP Deal Process?

After a Biotech has granted access to one or more Pharmas...

Mid-stage/Due Diligence

- External advisors, such as investment banks manage the CP deal process and prepare/organize non-confidential and confidential information to share with the Pharma Company
- Internal executives from the Pharma company, such as scientists/clinicians and members of the Business Development Team, conduct due diligence on Product X by analyzing the prepared business/scientific/financial materials (physical or within an electronic dataroom)

Final-stage/Negotiation

- Lawyers on both sides review legal documents and assist in revising those documents to protect the client's economic, commercial and technological interests
- The Biotech and Pharma financial teams support the investment bank in negotiating terms of the Corporate Partnering transaction, leading to (hopefully) a signed deal