



David Wallis and Jan Heybroek

Whether you're on the inlicensing or outlicensing side of a collaboration, attention must be paid to putting forth the right image and learning about your prospective partners before the alliance is struck.

David Wallis is a partner at the Dechert law firm, 2 Serjeants' Inn, London EC4Y 1LT UK, 44.207.583.5353, fax 44.207.353.3683, david.wallis@decherteu.com, www.dechert.com.

Jan Heybroek is engagement director of Cambridge Pharma Consultancy, 1 Quayside, Bridge Street, Cambridge CB5 8AB, UK, 44.1223.350.553, fax 44.1223.315115, jan_heybroek@cambridge-pharma.com, www.cambridge-pharma.com. The information and expressions of opinion contained herein are not intended to be a comprehensive study nor to provide legal advice and should not be treated as a substitute for specific advice concerning individual situations.

Becoming a Partner of Choice And Evaluating Prospective Alliances

The past five years have seen a rapid increase in the number of partnerships forged between big pharma and biotech (Figure 1). Most alliances are struck either during the discovery stage or at the time of product launch, suggesting that two key incentives drive the phenomenon: generation of growth, either through increased funding (for biotechs) or additional late-stage projects (for big pharma); and addressing organizational weaknesses. Tough competition for biotech partners with the best technologies or products has forced up the average dollar value of alliances. The success or failure of collaborations is having an increasingly significant profit and loss (P&L) impact, with 30% of pharma revenues already derived from licensed products and 90% of biotech funding currently sourced through alliances.

To compete in this changing environment and be positioned as the partner of choice with key strategic players, management should review their companies' approaches to mapping out, establishing, and managing alliances. Becoming the partner of choice and maximizing the value obtained from alliances involves five key steps: determining strategic partnering objectives, understanding the value brought to the alliance, identifying and understanding potential partners, promoting capabilities to potential partners, and realizing maximum value from the partnership (Figure 3).

Determining strategic partnering objectives. Partnerships must achieve strategic corporate objectives if they are to bring any added value to an organization. The first step in any partnering strategy is to lay out the alliance objectives, the specific purpose of entering into the partnership. A structured approach to this task may include strategic visioning exercises, which provide a useful tool for breaking down long-term corporate objectives into near-term intermediate goals and specific activities. An alliance should address those goals that the company cannot

achieve on its own, and gap analysis provides a useful measure of how well the objectives of the alliance truly align with those of the organization.

Prioritizing alliance objectives provides further clarity on which capabilities the partner must possess for a deal to be considered — and which aspects are most desirable — but should allow for some flexibility. With alliance objectives established and prioritized, a foundation is in place on which to build a partnering strategy.

Understanding the value brought to an alliance. Reviewing and evaluating its own capabilities allows a company to determine the value it offers potential partners. By analyzing its profile and objectives, management will be better positioned to present these capabilities in the most attractive format. However, only by stepping into the shoes of your potential partner can you really understand which factors are key to selling the deal. Time invested in the prenegotiations to gain knowledge of such "hot buttons" will yield future dividends.

A capabilities matrix (Figure 2) is a management tool that can help analyse both companies' strengths and weaknesses (either in therapeutic areas or more generic functions) and assess in detail the potential value of a company's capabilities to its prospective partners. Visualizing exactly how the two organizations will mesh helps management structure a deal that will optimize the benefit to both parties, reinforcing a company's standing as the partner of choice.

Competitor analysis helps in determining which corporate capabilities can be leveraged. A franchise in a specific business area (defined as a company's ability to add more value than its competitors to a particular customer group) is especially desirable, and optimal franchise marketing adds considerably to the value proposition.

The output of your strategic planning will be a portfolio of capabilities that can be leveraged to competitive advantage.

Structured Interactions

Because strategic alliances can hinge on personal relationships, partners of choice develop a formal structure for interactions between companies.

Maintaining regular contact facilitates good communication and paves the way for future relationships by allowing both parties to gauge where and how an alliance may bring potential benefits

Monitoring progress. Developing a structured relationship management system to monitor contacts helps flag opportunities

Identifying and understanding potential partners.

Identifying which partners will enable your company to meet its objectives requires more than desk research and abstract evaluation. In most cases the likely success of a partnership, and much of the value eventually gained from it, is determined by soft factors such as personal relationships. It is important to identify potential partners through personal contact — although other communications tools (such as PR, websites, and so on) provide useful support.

The power of personal contact should not be underestimated. It not only enables a relationship to form before the formal alliance is brokered, but also provides an opportunity to assess the organization and its specific capabilities, technologies, or products of interest — often based on confidential information. Furthermore, it enables the potential partner's needs to be clearly identified and understood, allowing your company to outline the value of its capabilities at the same time. That should create a firm basis on which to build any future alliance negotiations.

To overlook the element of personal contact would mean basing judgments solely on data available in the public domain, and they are by definition out of date and unlikely to be wholly accurate. No matter how thorough your research, it cannot provide the competitive advantage gained by forming close, personal relationships with target companies.

Having assessed a potential partner's capabilities and ability to meet your own strategic needs, analyze its alliance history and preferred approach to potential partnerships. Many biotechs now look

for collaboration to different functions within each company.

Coordinating communication. Mixed messages or multiple contact points cause confusion and hinder the relationship. Designating key personnel for channeling or coordinating communication facilitates navigation through foreign organizational structures and ensures consistency in the corporate messages being relayed.

beyond the traditional formula of up-front payments, milestones, and royalties when structuring deals. You may seek a mix of financial structures and other elements, such as equity investments, loans, and product exchanges. Being flexible enough to structure objectives to best fit your partner's corporate profile and strategy will count strongly in your company's favor and enhance the probability of securing the alliance deal.

Promoting capabilities to potential partners.

Alliances are an advanced and often highly complex business relationship. Promoting company capabilities to potential partners is essentially a marketing exercise, which implies that two important factors should be addressed: creating value messages that are specific to each potential partner, well communicated, and clearly understood; and developing a marketing strategy tailored to

Maintaining the Relationship

If a partnership strategy is not proving successful, some modifications may be necessary. Here are some common approaches.

Communication methods may have to be retailored to the target organization. Different promotional methods or angles of approach might prove more fruitful.

The **value proposition** may need refining to best package your company's capabilities. If it does not currently meet the partner's requirements, some elements may be added or developed to enhance its image as an optimal alliance partner.

Managing the Relationship

A number of processes can help both parties maximize the value of an alliance.

Tracking the performance of the company and partner against alliance objectives ensures that both parties are delivering on the promises and commitments made during negotiations and allows issues to be addressed proactively.

Alliance management should be well organized and properly resourced.

Regularly assess the value proposition and partner interactions.

each target partner and the "package" of capabilities being offered. Fostering close company relationships will not only help you identify and assess potential partners but

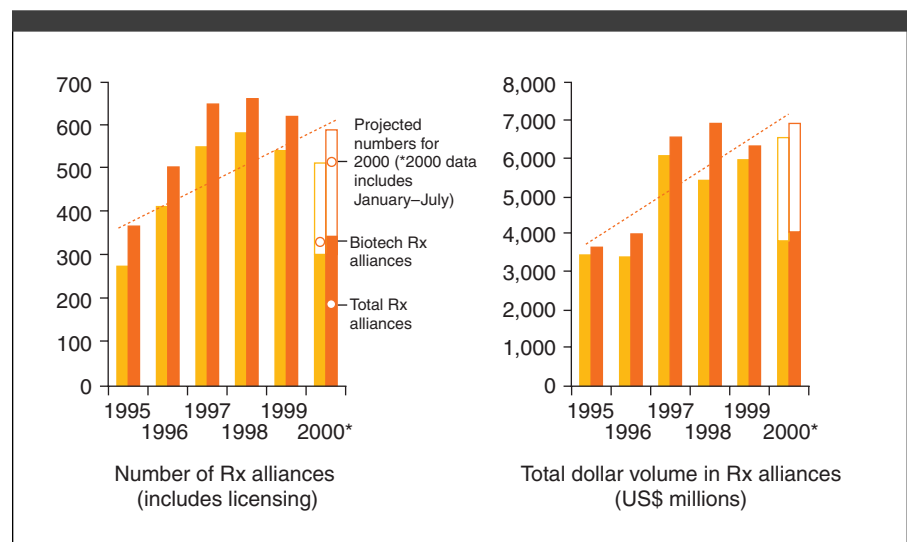


Figure 1. Number of alliances and their total dollar volume (1995–2000)

Managing the Lawyers

Your company's lawyers must understand what important information and documents should be requested when performing due diligence. Lawyers should not incur unnecessary expense or give rise to delay by asking for unimportant information or reviewing documents that could more properly be reviewed by others (such as management or other advisers).

Let them know up front what type of report management wants to see on the results of their search: an oral report alone or followed by a written document (and how detailed should such a written report be?). And give them a timetable for the transaction, and therefore a deadline for completing their report — sufficiently ahead of the projected date for exchange of contracts so that the company can act on any problems in good time. Lawyers work better to a timetable, but it is important to ensure that timings are realistic. They have a developed sense of timing and usually can make an informed guess about when a timetable can not be achieved.

will also provide a channel through which to communicate your company's value messages and promote internal company capabilities.

This approach offers additional advantages. Given the undoubted importance of alliances to achieving corporate strategy, CEOs and senior alliance personnel often cite "showing commitment" as the number one attribute they look for in prospective partners. Prealliance relationships serve to demonstrate the long-term interest and commitment to a product or technology that many partners desire. Good relationships may mature into

important alliances further downstream, and they are best constructed by implementing a more formal structure to company interactions. The "Structured Interactions" box lists three key aspects of such communication.

Realizing maximum value from the partnership.

Maximizing value from alliance-based strategies requires a continuous cycle of review and optimization. Constructing a management "dashboard" ensures that all relevant alliance metrics are measured at the appropriate time. See the "Maintaining the Relationship" box for more advice.

Why Due Diligence?

Due diligence in this context refers to the investigation of a company (or a specific asset belonging to that company) by or on behalf of a prospective buyer, investor, or collaborator. Although the method of investigation and the personnel involved may vary, due diligence essentially takes the form of seeking, reviewing, and reporting information. Effective due diligence should be a structured, systematic research effort to accumulate the information needed to make an informed decision regarding an acquisition or collaboration, thereby increasing the chances of a successful transaction on the right terms.

Understanding the partner's business and avoiding unwelcome surprises. Even if a company and proposed partner are involved in the same general business, one is unlikely to have any detailed knowledge of the particular way in which the other operates.

Due diligence gathers valuable know-how to develop a better understanding of the other party. It provides comfort that the investment will be secure and that the potential partner has the necessary IP rights, personnel, expertise, and resources to perform its alliance obligations. In addition, it instills into both companies the confidence to arrive at their final pricing terms — or to

			Rheum	Oncology	CY	CNS	etc.
Development	Marketing						
	Regulatory (submissions)						
	Clinical	Phase III					
		Phase IIb					
	Commercial manufacturing						
	Clinical	Phase IIa					
		Phase I					
		Regulatory (trial design)					
	Preclinical	Pharmacology					
		Clinical trial supply					
Formulation							
Toxicology							
Process development							
Research	Lead identification and optimization	Drug design and engineering					
		Target libraries/bioinformatics					
		Combi Chem					
	Target identification and validation	HTS					
		Genetics/genomics					
		Proteomics					
		Disease pathology					
		Target Ip					
Available target pool							

* This matrix helps to assess company capabilities per therapeutic area and estimate its value to potential partners.

* Capabilities of interest to a potential partner may well be outside the therapeutic area of the licensing opportunity.

Figure 2. Identifying corporate capabilities using a capabilities matrix for a sample incensing company

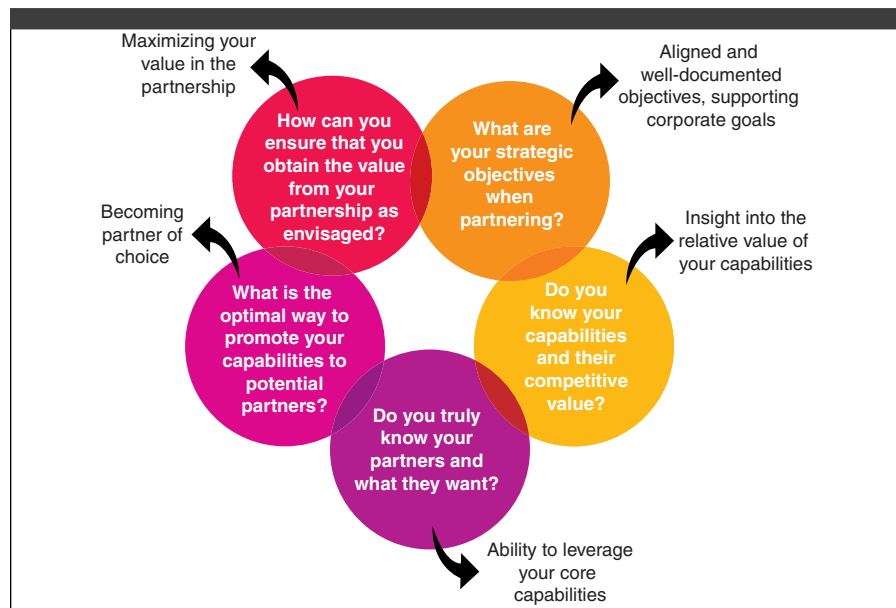


Figure 3. Key factors in identifying and planning strategic alliances

seek a price reduction for previously unforeseen risks or problems.

Deciding whether to proceed. A fundamental purpose of due diligence investigations is to enable a company to decide whether to proceed with a transaction. It may be interested in collaborating with another organization only if satisfied about a particular aspect of its business (such as patent rights or the real status of drug trials). If a potential problem is discovered before the contract is signed, the company may be able to adjust the financial terms of the collaboration or require that the problem is resolved satisfactorily first. Ultimately, of course, management can make an informed decision not to proceed with a deal.

Streamlining preliminary planning and practical considerations. Due diligence exercises vary in the range of matters reviewed, in the intensity of that review, and in the personnel involved. Before commencing investigation, it is therefore extremely important to draw up a comprehensive plan that identifies exactly what is to be reviewed and who is responsible for reviewing it. Obviously, persons with the appropriate expertise should review relevant information. Such considerations should be taken into account during the preliminary meeting(s). Among other advantages, such meetings allow the members of transaction teams to fully understand their own and each other's roles in the performance of due diligence, thus avoiding unnecessary duplication and misunderstanding.

Each due diligence plan must be tailored to the specific circumstances of the transaction. There is a real need to separate the wood from the trees, and time invested in getting the process right from the outset is time well spent.

In addition to external due diligence advisers (see the "Managing the Lawyers" box), a company's own management team plays a crucial part in due diligence. They may be the only people who can appreciate the full importance of certain trade or business information obtained. Their knowledge and understanding of the business may secure more information from a proposed partner's management (who may be more forthcoming "between businessmen"). They can also help their due diligence advisers focus on particular corporate matters that are most important.

Know the partner. As well as due diligence in the obvious areas such as intellectual property (IP, including coverage, territory, ownership, validity, and infringement of patents), the importance of due diligence on the proposed partner itself cannot be underestimated. You must know the true financial position of a proposed partner or, more specifically, the ability of that partner to carry out its obligations and meet any damage claims. Little is gained from having a carefully negotiated collaboration agreement if the company in question does not have real assets to meet any claim of damages or does not truly own the

technology that is the subject of the collaboration.

Compare, for example, a large pharma company with a family-owned pharma. Each entity may have a labyrinthine corporate (or partnership) structure, with different entities owning IP rights and real property, so it is clearly important to include them in the equation; in other words, "Show me the money" (and underlying assets). Another key area to test is whether a proposed partner is "clean." Does it have a good inspection record and follow GMPs? Have clinical trials been compiled in accordance with applicable law?

Managing Risk

Contractual protection is no substitute for a thorough due diligence exercise, but it may offer some comfort if time is short and due diligence is limited. Under such circumstances, it is prudent at least to investigate key issues and take other precautionary protective measures. For example, ensure that warranties and indemnities are appropriately wide. Consider a mechanism for adjusting or repaying milestone payments to cover warranty claims — or provide some other mechanism for adjusting the financial elements of your collaboration after completion of the deal. That may include "put/call options." Make provision for known, identified, and potential problems to be solved as preconditions to completing the deal.

No amount of due diligence can ever provide a definitive answer on patent infringement. It is both impossible and impracticable to "research the world." Clearly, care must be taken to establish that rights arising from any third party expertise or cooperation obtained in product development truly lie with the proposed partner.

Product liability insurance. Allocation of risk in relation to product liability is a very contentious issue. The ability to shift some risk away from the alliance partners to an insurance company is worthy of consideration. That would enable curtailing the scope of review in a way that is financially prudent. Explaining to an outlicensing partner that product liability insurance will be used (and the premiums

Continued on page 60

Process Development

Becoming a Partner of Choice continued from page 42

deducted proportionately from milestone or other payments) often shortens negotiation of the agreement.

However, class action suits in the United States have made an already nervous insurance market rather more jittery, leading to availability and cost issues.

Other options. The same principles used in the leverage buy-out world, where venture capitalists and banks join forces to complete large-scale deals, can apply in pharma–biotech collaborations. The greater the number of participants, the greater the ability to share and allocate risks. And perceived risks in manufacturing can be managed by outsourcing particular manufacturing processes away from a proposed partner.

A Two-Way Street

Becoming the partner of choice is a process of evolution. It takes time to acquire a reputation. Many elements of partnering strategy can be implemented rapidly, others must be optimized through iteration.

The current environment is driving a need for greater interreliance between biotech and big pharma. Establishing and managing an alliance strategy that will attract key strategic partners (Figure 3) is an essential corporate capability. The gap in financial success between companies that effectively position themselves as the partner of choice and those that do not will inevitably widen.

Due diligence is an essential component of the acquisition or collaboration process. Its purpose is to enable prospective buyers, investors, or collaborators to better understand the implications of their deals and ultimately to decide whether or not such deals are in their interests. A streamlined

due diligence process requires clarity of organization and responsibilities within the management team of each buyer or collaborator and clear instructions to external parties such as lawyers acting on their behalf.

A core part of the due diligence effort is to verify a potential partner's financial position and examine other key issues such as the status of its IP. The process will also highlight risk. If the deal is still fundamentally desirable, it may then be appropriate to explore ways to offset at least part of that risk. **BPI**

Reference

- (1) Conference Proceedings, *Biotech/Pharma Partnerships: Maximising Value, Minimising Risk* (Cambridge Pharma Consultancy, Cambridge, UK, November 2001).