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Strategies and tactics for successful partnering

A guide to partnering pharmaceutical and biotechnology projects

A PharmaDeals Report

edited by Heather Cartwright & Taskin Ahmed

Strategies and Tactics for Successful Partnering

A Guide to Partnering Pharmaceutical and Biotechnology Projects

Edited by
Heather Cartwright and Taskin Ahmed

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Executive Summary

Strategies and Tactics for Successful Partnering: A Guide to Partnering Pharmaceutical and Biotechnology Projects is a practical source of information whether you are experienced or new to business development in the industry. It provides you with in-depth insights into all the different stages of the partnering process and answers key questions such as:

- Why is partnering so important?
- What issues should I consider before partnering my project?
- How do I find a partner?
- What is the best way of presenting my partnering opportunity?
- What is the best way of presenting my company?
- How should I value a partnering project?
- How would I negotiate a deal?
- What due diligence do I need to do?
- How do I manage the partnership after the deal is signed?
- What should I do if the partnership isn't working?

This report discusses these issues and many more, and includes hands-on advice on how to complete each of these activities. This includes directing you to appropriate resources and providing detailed guidance on how to complete each activity. For example, in addition to discussing what confidential and non-confidential material should be prepared to partner a project, it also outlines in detail what each of the documents should contain.

An overview of the partnering process is included so that if you are less familiar with this area, you can understand the steps that are involved in partnering a project and how these may vary between different companies. The experience of partnering with a big pharmaceutical company can also be quite different from partnering with a small biotechnology company and there are specific chapters providing insights on how the partnering process works in each of these types of organisation, and how you can work best with each of them.

In an increasingly competitive environment for partnering, it is also important for companies to explore how they can attract unsolicited partnering approaches, in addition to being able to identify partnering opportunities. How to build a reputation as a 'partner of choice' is explored further.

Different types of deal will involve different levels of partnership, with some requiring little co-operation once the contract is signed, while others may require the parties involved to work together very closely for many years. An overview of the different types of partnering deal that are available is included, along with the rationale for choosing each type of deal and key points that should be considered.

As part of securing the deal, practical guidance and advice are provided on how to negotiate a deal. Detailed lists of due diligence questions are also supplied which you can use to support your own due diligence activities, or to prepare for a partner completing due diligence on one of your own projects.

The day that the contract is signed is in reality the first day of the actual partnership and the report explains the life cycle of a deal. Too often all the emphasis is put on signing the deal and little attention is paid to how to actually manage the deal post contract or, more significantly, how to build in elements throughout the partnering process to give you the best chance of successfully establishing and managing the partnership so that it will realise its maximum value. Lastly, should the partnership enter difficulties the report includes guidance on how to deal with conflict in partnerships. In the event that conflict management techniques are not successful, an overview is also included of mediation, arbitration and litigation.

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1 An Introduction to Partnering

This report has been written to help you successfully complete partnering deals. It is a wide-ranging document that covers many different aspects of partnering. After reading it you will have a better understanding of how partnering works and how best to complete the process to realise the full value of your partnering deals. This introductory chapter gives you some background information on what partnering is, why companies partner, an overview of the different types of partnering deals that you can use, who partners with whom and what are the general trends in partnering.

1.1 What is Partnering?

> *'Partner – A person who takes part in an understanding with another or others, especially in a business with shared risks and profits'*
>
> Oxford English Dictionary

In a partnership, two or more parties are working together in an area in which there are shared risks and rewards.

Many different types of partnership exist in the biopharmaceutical industry. These can range from an early-stage research collaboration between a biopharmaceutical partner and an academic research unit to a co-promotion agreement in which two companies are working together to sell the same marketed product.

The way in which the risks and rewards are divided in the partnership can vary greatly, depending on the type of deal signed. For example, any shared profits may be in the form of a division of royalties, or in a joint venture there may be a true sharing of both profits and risks. A common factor in all these many different forms of partnerships is the long-term relationship between the parties. This is a key issue that will be visited again in this report.

In the case of 'one-off transactions', such as acquisitions, you could argue that the buyer's ultimate goal is to acquire the assets for sale at the lowest possible value that can be negotiated. Such a negotiation could be very aggressive and one-sided, resulting in considerable ill-feeling and antagonism in the seller. However, the buyer may feel that as no further dealings are intended with the selling party in the future,

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this is of little consequence. Such a mindset has no place in the establishment of a successful partnership, where the goal must be one of securing a 'win–win' deal between the two parties. In a true partnership each party benefits from the shared rewards created by the relationship.

1.2
The Partnering Process

As Figure 1.1 shows, partnering involves a deal process chain. At the start of this is the 'want' phase, i.e. the strategic desire to bring a new project into the portfolio. This is followed by the 'find' phase, where potential partners and targets are identified. In the 'get' phase the opportunities identified are evaluated and negotiations are held. Finally, there is the 'manage' phase, where the alliance or collaboration must be managed. This is a long process that often results in a long-term relationship between the partnering companies.

To complete a partnering deal you will have to complete each of these steps successfully.

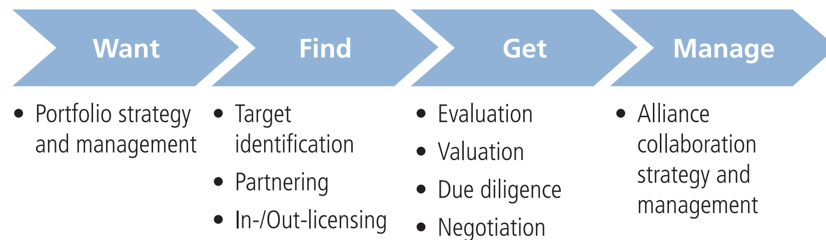

Figure 1.1 – The deal process chain.

1.3
Why Do Companies Partner?

Many believe that partnering in the biopharmaceutical industry has never been more important than it is today. However, this situation is not unique to the biopharmaceutical world. The business environment across many industries is now global and characterised by intense competition. To improve their chances of survival, companies worldwide are increasingly forming strategic alliances with their competitors, suppliers and, in some cases, their customers.

However, irrespective of the industry in question, partnering activities should be undertaken with the aim of delivering results that are in line with, and help to achieve, a company's corporate strategy. This can range from simple survival for an early-stage biotechnology company, to the achievement of ever-challenging revenue targets in an established pharmaceutical company.

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The biotechnology and pharmaceutical industries are experiencing challenging times and there are a number of industry pressures that are driving an increase in partnering. These include the patent expiry of valuable drugs, the steady state of products in development and a still challenging market for fundraising for biotechnology companies.

The patent cliff is set to reach a peak in 2012 with US$33 B worth of drugs coming off patent, including four of the industry's once top-10 best-selling medications. These patent expiries are depressing big pharma revenues and prompting these companies to expand their pipelines and diversify their operations, typically through alliances and acquisitions. As rates of generics utilisation continue to increase, some pharmaceutical companies are looking to new sources of revenue such as branded generics and biosimilars and many are targeting high-growth emerging markets. There is also a shift away from small molecule therapeutics that target large primary care markets to biological therapies that address more niche patient populations.

In spite of high levels of R&D spending, improvements in discovery and screening technologies, mergers and acquisitions and restructuring of R&D functions, the number of approvals of new molecular entities (NMEs) has held steady in recent years, with no significant upturn to help offset falling drug sales (*Figure 1.2*). One reason for this is that the number of applications filed for NMEs has also not been substantially increasing. Nevertheless, 12 of the 30 NMEs approved by the US FDA in 2011 were first-in-class and 11 were to treat orphan diseases. What is more, IMS Health predicts that global launches for NMEs will rebound during the next 5 years, with 32 to 37 NMEs expected to be launched per year through 2016.

Alongside this current shortfall in product numbers, biotechnology companies have also been finding it difficult to raise funds. Although 2011 appears on first inspection to have been a good year for biotech financing, the increase in capital raised is mainly attributable to debt as more established commercial biotech companies took advantage of low interest rates to raise large amounts of debt (*Figure 1.3*). In spite of the global economic crisis, venture capital financing has actually remained steady in recent years, although a sizeable proportion of the total capital raised per year is attributable to a relatively small number of companies.

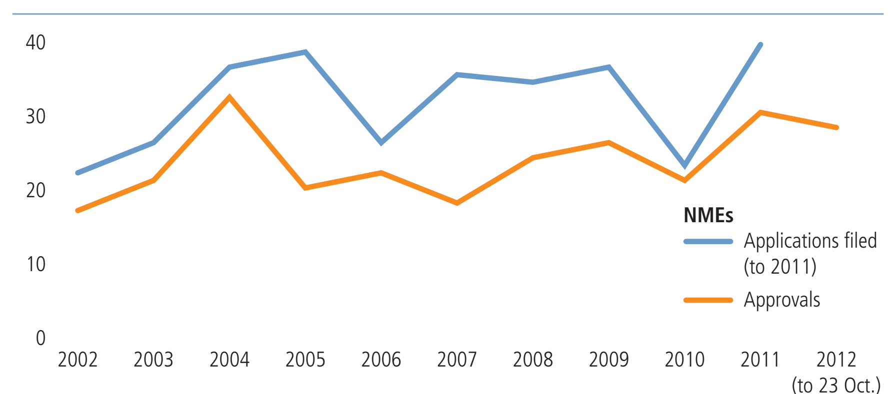

Figure 1.2 – Steady rate of development of new drugs.
Source: US FDA

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2
When to Partner and How to Find the Right Partner

The decision to partner a project is not always an easy one and there are a number of factors that you should consider. Having decided to partner a project, you need to identify suitable partners. This chapter provides an overview of the types of issues that you should consider when deciding to partner and advice on how to find the right partner.

2.1
When to Partner

Choosing the best time to partner is critical and getting it right will significantly affect the strategic options available in the future and may be the difference between success and failure for your company, particularly if you are a small company completing your first partnering deal. If you partner a project too early it is likely to have a lower value, while leaving the decision too late can be risky, and financial or strategic issues may mean that you then need to find a partnership deal in a hurry. This may ultimately be hard to do if your clinical results were not as positive as you had hoped, and the value of the deal, or the selection of the best partner, may be compromised.

Your selection of the best time to partner a project will be affected by a number of factors that are discussed below.

2.1.1
Project Phase

Partnering deals are completed at all stages of the R&D process. However, some development stages are more popular than others.

Figure 2.1 shows that 21% of all deals in the *PharmaDeals® v4* database since 2001 are for projects at the discovery stage of development. Together with the number of preclinical deals, early-stage dealmaking represents nearly 40% of all deals demonstrating that some biotech companies are having to partner earlier due to the difficult funding environment especially in recent years. On the flip-side, large well-funded pharma companies are interested in taking on the risk of early-stage development projects in key therapy areas but mitigating their risk via option-based deal structures.

3
The Partnering Process

Licensing is a very competitive activity and the quality of the information you produce on your product or company can make a significant difference to the success of your partnering discussions. In particular, it can determine whether your project catches the attention of potential partners so that you can have an initial discussion or whether it is simply discarded at the first stage without a fair review.

When you are preparing the necessary documentation it is important to remember that this is ultimately a selling exercise and your material should present an accurate, but positive, case on the merits of your project or company. It should present the facts in a clear and straightforward manner and should avoid exaggerated claims and sales predictions, as nothing turns a busy licensing executive off faster.

This chapter includes an overview of the sequence of contacts that will be made between the parties when establishing partnering agreements and the material that you should prepare to support these discussions.

3.1
Sequence of Contacts

There are a series of potential contacts that will be made between partners when establishing a partnering agreement. However, different companies will follow slightly different sequences, and Chapters 4 and 5 discuss some of the elements that may vary between a major pharmaceutical company and small biotechnology company. In general though, the process will contain the steps outlined in Figure 3.1.

3.1.1
Initial Approach to Potential Partners

In an ideal situation, the initial discussions are held between two individuals who already know each other. For example, you may have already met at a licensing conference or other networking event. It is also invariably quicker and easier to complete a deal with a company with whom you have held discussions previously, particularly if this led to a signed contract, as trust has already been established. Similarly, external consultants can add value at this stage as they can access their personal networks of contacts, which may be far larger than your own.

7
Valuation

A variety of methods are available that purport to provide valuations of products and/or technologies. These range from arbitrary or traditional rules of thumb, through analyses with various levels of rigour, to somewhat esoteric methods that can obscure rather than illuminate the value creation process. Using the most appropriate valuation methods is critical as getting the value of your deal right. This chapter provides an overview of the key deal valuation methods used in the pharmaceutical industry from PharmaDeals' publication *Approaches to Valuation of Pharmaceutical Licensing Deals*. A more detailed analysis of the valuation methods discussed can be found in this report.

7.1
Combining Valuation Techniques

No single valuation method is sufficient alone. However, two methods in combination – the Benchmarking Method and the expected Net Present Value (eNPV) Method using Discounted Cash Flow (DCF) and Decision Tree Analysis (DTA) – often suffice to provide managers, negotiators and decision makers the information they need to value projects whether it is for portfolio management or for dealmaking purposes. This is the traditional approach used in the pharmaceutical industry and you are likely to find that your partner company will employ this methodology. By using these methods together, you can use each to inform and cross-check the other (*Figure 7.1*).

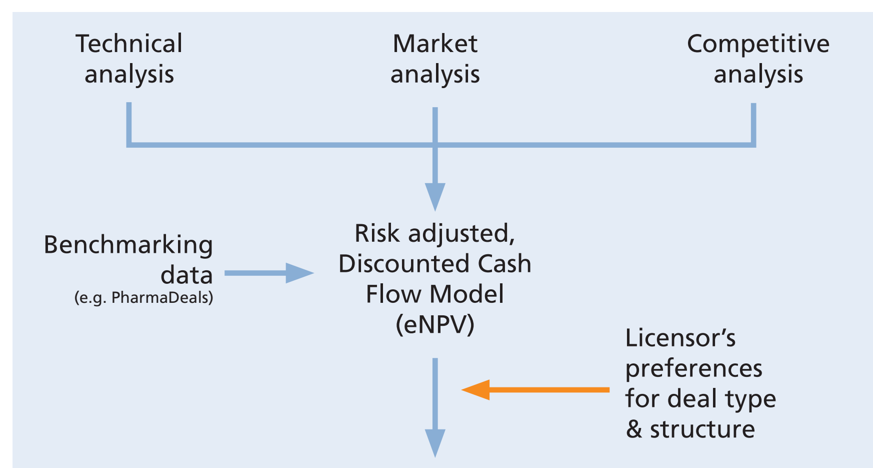

Figure 7.1 – Integrated valuation methods.

8
Deal Structure

The range of partnering deals that you can use is wide and varied – from a small feasibility study to a co-marketing arrangement for a launched product. There is also a big difference in the level of co-operation and partnership required in these different deal structures, and you must select the most appropriate structure for your project and strategic goals.

Even the most experienced pharmaceutical manager is unlikely to have been involved in each and every type of deal. This chapter provides an overview of the different deal structures in both the R&D and product licensing stages, and includes extracts from the PharmaDeals' publication *Trends in Pharmaceutical Dealmaking: An Analysis of Valuations, Deal Structures and Deal Types*. More detailed discussions of the deal structures presented below can be found therein.

8.1
Evolution of Partnerships

Doz and Hamel† described how the typical objectives of a partnership evolve along the various stages of the development and evolution of an opportunity. It shows that the early years, when sales are non-existent and cumulative cash flow is negative, is a time to secure funding from venture capital, initiate R&D collaborations and to establish alliances to share risks. As sales begin to enter the growth phase, key partnerships can be established to acquire complementary skills and products to support sales and alliances are formed that help to expand into new markets. In later years when sales begin to decline in the product maturation phase the business seeks to stabilise its position in the market against the competition.

Although not all situations follow such a neat sequence, it does highlight the fact that the strategic compatibility of an alliance will be changing as the strategic priorities of the partners shift independently of the alliance, and the alliance will fulfil different needs at the various stages in the opportunity.

Although this presents a general industry model, it is important to remember that a pharmaceutical partnership will also evolve as a project moves through the different stages of the R&D programme. For example, what may have started as a simple technology access agreement could subsequently become a full-blown co-development partnership. Therefore, not only must you select the most appropriate deal structure initially, but you must also carefully manage its evolution and revise it as necessary.

† *Alliance Advantage: The Art of Creating Value through Partnering* (1998, Harvard Business School Press)

For the potential licensor, feasibility studies provide an opportunity to draw in potential partners who may otherwise be too cautious to commit to a licensing deal.

8.5 Technology Access Agreements

Technology access is a process whereby one company pays another company or individual for the ability to utilise its technology, usually by means of licensing with no further research involvement by the licensor.

Platform technologies have played an important role in drug discovery in recent years where companies look to refill their dwindling pipelines. The techniques involved have become extremely sophisticated and expensive. Large companies now frequently gain initial access to platform technologies via technology assessment agreements. In some cases these technologies are integrated into in-house capabilities, eliminating the need for long-term agreements.

Technology access suits large companies as there is no real dependency between the two companies. It also suits platform technology companies as technology access deals are typically non-exclusive so multiple deals can occur, generating multiple revenue streams.

Advantages	Disadvantages
To gain commercialisation expertise in a new therapeutic area	There may be confusion with multiple brands for the same product
To access resources and expertise in a geographical area in which the licensor lacks the local infrastructure and local knowledge	There is reduced promotion for a single brand
To bring in additional resources when a product requires a significant sales and marketing effort	If the brands are marketed at different prices, the price will become confused
To build a rapid adoption in the launch phase of a product in a competitive market	There may also be potential infighting between the co-marketing companies for brand share
To promote a product that has multiple delivery forms	
To promote new formulations of a drug	
To promote an established drug in new indications	
To reduce pre-marketing costs by sharing them between the parties	
To establish a sales and marketing infrastructure in a smaller company which would not be able to do it alone	

Table 8.2 – The positives and negatives to consider when entering into co-marketing agreements.

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9
Securing the Deal

This chapter describes the activities involved in the due diligence process and the types of questions that must be answered so that you can be prepared for it, either as the party completing it or as the party on the receiving end of it. Once a due diligence exercise has been satisfactorily completed, you may then wish to enter into negotiation, which represents a key aspect of partnering. You may have the best product in its class, but if you are a poor negotiator, you may not end up with the best deal for it. This chapter also provides an outline of the various stages of negotiation, guidelines on how to negotiate the financial terms for a deal and some insights into the different types of negotiation behaviour that you may come across.

9.1
The Due Diligence Process

The process of due diligence starts, in many ways, from the point of first contact between the two parties because they will immediately start to share information, albeit initially non-confidential information. It is useful to bear this in mind, whether you are involved in an in-licensing or an out-licensing project. In an in-licensing project you should immediately start gathering information from the time of first discussions, while when out-licensing you should be aware that whatever you say about the project at any stage can be used by the other company as part of the information available to evaluate the project.

It is also important to remember the Latin phrase 'caveat emptor', meaning 'buyer beware'. This is the idea that in a transaction buyers take responsibility for the condition of the items they purchase and they should examine them before they do this; this is especially true for items that are not covered under a strict warranty. In pharmaceutical agreements the licensee should complete a thorough due diligence exercise to examine the project fully, and use warranties and indemnities to protect themselves further.

The due diligence process can be a lengthy and costly one. For this reason, as discussed in Chapter 4, some companies prefer not to complete a full diligence until they have agreed the deal terms, then the deal is 'subject to satisfactory due diligence'. Other companies prefer to complete the due diligence before agreeing the terms.

10
The Deal Life Cycle

This chapter provides an overview of how to manage a partnership after a deal has been signed and how to try and resolve conflict should it arise. This includes an insight into the type of discussions you will need to have with your partner, and the clauses that should be included in the contract should you ultimately find that you have no option other than to terminate the deal. It also includes some examples of the type of litigation that can arise from such conflicts, and the mediation and arbitration techniques that you can use to hopefully avoid things ever reaching this stage.

10.1
Alliance Management

Pharmaceutical companies, in particular, recognise the need to address the issue of how to unlock the maximum value from their alliances. Many are taking steps to improve their alliance management capabilities in order to protect their investments and position themselves as more attractive partners in a competitive licensing and dealmaking market. Alliance management not only provides a competitive advantage in winning new deals, but also creates a discipline beyond the present project management systems.

If you are in a large organisation you may have a formal alliance management structure in place. However, this is unlikely to be the case in a smaller biotechnology company. Although it may not be practical to establish such an infrastructure in a small company, it should be possible to incorporate some of the philosophies and activities that are well developed in some of the larger companies, into your own smaller organisation to maximise the value of your partnering activities.

10.2
Process Risk and Performance Risk

Process risk refers to those risks that are created by how the partners manage the alliance and comprises two elements: performance risk and relational risk. Performance risk refers to how well the partners manage the alliance given a good relationship. Relational risk refers to issues originating from a poor relationship

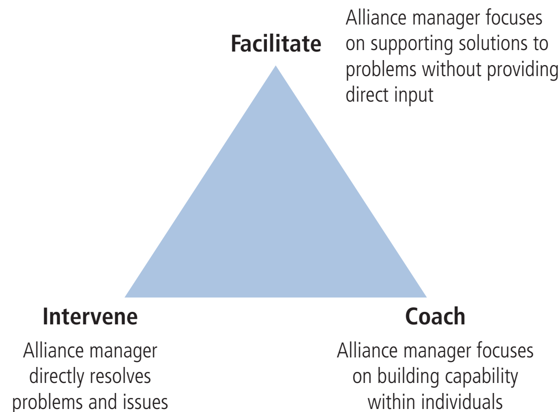

Figure 10.3 – The roles of an alliance manager.

It can be helpful to think about the role of the alliance manager in terms of the level of co-dependence in the collaboration you are establishing. Alliances with high co-dependence have a greater need for good alliance managers playing an active role in the collaboration. In low co-dependence alliances the alliance manager may take on more of a monitoring/decision-making role. You should consider how closely your alliance manager needs to work with members of the project team according to the type of partnering deal that you have signed.

10.6 Key Factors for Success

One question that often gets asked is 'What factors should we concentrate on to get the alliance structured and launched right?' There are five themes that are critical for this purpose, namely:

- Governance
- Communication
- Alliance start-up
- Measurement (*see Section 10.7*)
- Process integration

10.6.1 Governance

The alliance agreement typically provides an appropriate framework for the project team as it documents some of the governance issues, such as the formation of a governance committee. These are the joint steering committees formed to oversee the delivery of the partnering project. For a research collaboration this is likely to be a Joint Research Committee, while for a co-development agreement, a Joint Development Committee would be established. These committees have joint membership from both companies, and some guidelines regarding their membership, function and governing rules may be laid out in the contract.

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