



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



Copyright © 2012 PharmaDeals Ltd

Published by PharmaDeals Ltd, now part of IMS Health
210 Pentonville Road, London N1 9JY, UK

Contents

Executive Summary	9
1	
An Introduction to Partnering	11
1.1 What is Partnering?	11
1.2 The Partnering Process.....	12
1.3 Why Do Companies Partner?	12
1.4 Types of Partnering Deal	15
1.5 Who Partners with Whom?.....	16
1.6 General Trends in Partnering	17
2	
When to Partner and How to Find the Right Partner	19
2.1 When to Partner	19
2.1.1 Project Phase	19
2.1.2 Project Exclusivity.....	21
2.1.3 Internal Issues to be Considered	21
2.1.4 The Final Decision.....	23
2.2 How to Find the Right Partner.....	23
2.2.1 Operational Capabilities	24
2.2.2 Therapeutic Expertise	24
2.2.3 Target Partner Profile	25
2.2.4 Cultural Fit	25
2.2.5 Relationship Fit.....	26
2.2.6 Ideal and Unsuitable Partners	26
2.3 Partner Identification	27
2.3.1 Databases	27
2.3.2 Company Websites.....	28
2.3.3 Academic Institutions	28
2.3.4 General and Industry Press.....	28
2.3.5 Regulatory Filings	28
2.3.6 Personal Contacts.....	29
2.3.7 Conferences.....	29
2.3.8 Consultants.....	29
2.3.9 Internal and External Experts	30
2.3.10 Unsolicited Approaches	30
2.3.11 Venture Capitalists.....	30
3	
The Partnering Process	33
3.1 Sequence of Contacts.....	33
3.1.1 Initial Approach to Potential Partners..	33
3.1.2 Non-Confidential Information Sent.....	35
3.1.3 Internal Review by Partner	35
3.1.4 Confidential Disclosure Agreement Signed	35
3.1.5 Confidential Information Supplied	36
3.1.6 Due Diligence	36
3.1.7 Deal Terms Agreed	36
3.1.8 Contract Negotiated.....	36
3.1.9 Alliance Management	36
3.2 Non-Confidential Information	37
3.3 Confidential Disclosure Agreement	38
3.3.1 One-Way or Mutual.....	38
3.3.2 Duration.....	39
3.3.3 Project Coverage	39
3.3.4 People Covered	39
3.3.5 Information Covered	39
3.3.6 Return of Confidential Information	39
3.3.7 Public Disclosure.....	39
3.4 Confidential Information.....	40
3.4.1 Cover Sheet	40
3.4.2 Summary Overview.....	40
3.4.3 Scientific Rationale	41
3.4.4 Therapeutic Rationale.....	41
3.4.5 Chemistry, Manufacturing and Control	41
3.4.6 Technologies and Drug Delivery Systems	41
3.4.7 Preclinical Data.....	41
3.4.8 Clinical Data	42
3.4.9 Regulatory Status	42
3.4.10 Pre-Marketing Activity	42
3.4.11 Trade Marks	42
3.4.12 Commercial Rationale.....	42
3.4.13 Patents.....	43
3.4.14 Future Plans.....	43
3.4.15 Licensing/Partnership Opportunity	43

3.4.16 Disputes	43	6	
3.4.17 References.....	43		Establishing your Organisation as the
3.4.18 Marketed Products	43		Partner of Choice
3.5 Corporate Presentation.....	44	6.1	Different Partners of Choice for Different
3.5.1 Company Background.....	45		Projects.....
3.5.2 Major Product Summaries.....	45	6.2	Characteristics of a Partner of Choice
3.5.3 Sales Infrastructure.....	45	6.3	Strategic Fit
3.5.4 R&D Overview	45	6.4	Internal Inefficiencies
3.5.5 Financials	45	6.5	The Importance of Alliance Management
3.5.6 Licensing.....	46	6.6	Promoting Your Capabilities
3.5.7 Current Agreements.....	46	7	
3.5.8 Partnering Strengths.....	46		Valuation
3.6 Managing Your Contacts	46	7.1	Combining Valuation Techniques
4		7.2	Benchmarking
Dealing with a Major Pharmaceutical		7.2.1	Feasibility
Company	49	7.2.2	Data Gathering
4.1 Background.....	49	7.2.3	Refinement of the Valuation.....
4.1.1 Initial Approach.....	49	7.3	Expected Net Present Value
4.1.2 Making the Right Contact	51	7.3.1	Opportunity Cost/Time Value.....
4.2 The Decision-Making Process.....	51	7.3.2	Risk
4.2.1 Initial Review.....	52	7.3.3	Decision Tree Analysis.....
4.2.2 Detailed Review.....	52	7.3.4	Sensitivity Analysis.....
4.2.3 Due Diligence.....	52	7.3.5	Monte-Carlo Simulation
4.2.4 Valuation.....	53	7.4	Value Distribution
4.2.5 Negotiation	53	7.4.1	Value of Deal Components.....
4.2.6 Approval Levels and Committees.....	53	7.4.2	Value Splits Sharing
4.3 Timings	54	8	
4.4 Culture.....	54		Deal Structure
5		8.1	Evolution of Partnerships
Dealing with a Small Biotechnology		8.2	Licensing Agreements.....
Company	55	8.2.1	Simple Licensing Agreements
5.1 Background.....	55		Scope.....
5.1.1 Initial Approach.....	56		Manufacturing and Supply
5.2 The Decision-Making Process.....	57		Trade Marks
5.2.1 Initial Review.....	57		Sub-licensing, Assignment, Change of
5.2.2 Detailed Review.....	58		Control
5.2.3 Due Diligence.....	58		Warranties and Indemnities
5.2.4 Valuation.....	59		Patents.....
5.2.5 Negotiation	59		Improvements
5.2.6 Approval Levels	60		Marketing
5.3 Timings	60		Upfront and Milestone Payments
5.4 Culture.....	61		Royalties.....
			Term and Termination Rights
		8.3	Collaborative R&D Agreements.....
		8.4	Evaluation Agreements.....
		8.5	Technology Access Agreements

8.6	Co-marketing and Co-promotion Agreements ..	85	10.5	The Role of the Alliance Manager	110
8.7	Marketing Agreements	85	10.6	Key Factors for Success	111
8.8	Product Sale and Purchase Agreements	86	10.6.1	Governance.....	111
8.9	Option Agreements	87	10.6.2	Communication	112
8.9.1	Option to Purchase.....	87	10.6.3	Alliance Start-Up	113
8.9.2	Option to License	87	10.6.4	Process Integration	113
	Option Period.....	88	10.7	Performance Management in Collaborations	114
	Deal Terms	88	10.8	Conflict Management.....	115
	Back-up Compounds.....	88	10.8.1	Anticipate and Prepare	116
8.10	Equity Investments.....	89	10.8.2	Intervene Early.....	116
8.11	Alternative Deal Structures	89	10.8.3	Take Appropriate Remedial Action	117
8.11.1	Drug Royalty Companies	89	10.9	Mediation and Arbitration	117
8.11.2	Risk Sharing Agreements with Contract Research Organisations.....	90	10.10	Litigation	118
8.11.3	Quids	90	10.11	Termination Clauses.....	119
8.11.4	Joint ventures.....	91			
8.12	Conclusion	91			
9					
	Securing the Deal	93			
9.1	The Due Diligence Process	93			
9.2	The Elements of Due Diligence.....	94			
9.3	Providing the Information	98			
9.4	Negotiation	99			
9.5	Preparation Phase	100			
9.6	Negotiation Phase.....	102			
9.6.1	Negotiating the Term Sheet and the Financial Terms.....	102			
9.6.2	Negotiation Behaviour.....	103			
	Compromise.....	104			
	Collaboration	104			
	Competition.....	104			
	Accommodation.....	104			
	Withdrawal or Avoidance	105			
9.7	Outcome Phase	105			
10					
	The Deal Life Cycle	107			
10.1	Alliance Management.....	107			
10.2	Process Risk and Performance Risk	107			
10.3	Alliance Life Cycle Model.....	108			
10.3.1	Negotiation	108			
10.3.2	Formation	109			
10.3.3	Management	109			
10.3.4	Termination	109			
10.4	Alliance Management Structure.....	109			

Tables

1.1	Biotechnology issue prices in 2012.....	14
2.1	Issues to consider when out-licensing and in-licensing a project.....	22
2.2	Checklist of questions to help evaluate in-licensing projects.....	23
2.3	Target Partner Profile.....	25
2.4	Corporate Culture Issues.....	25
3.1	Contents of a non-confidential document.....	37
6.1	Successful alliance fitness test.....	65
7.1	Overview of benchmarking methodology.....	69
8.1	Reasons a company would out-license or in-license a product.....	80
8.2	The positives and negatives to consider when entering into co-marketing agreements.....	84
8.3	The positives and negatives to consider when entering into co-promotion agreements.....	85
8.4	The positives and negatives to consider when entering into marketing agreements.....	86
8.5	The positives and negatives to consider in option to license deals.....	88
9.1	Key areas for consideration in a due diligence exercise.....	95

Figures

1.1	The deal process chain.....	12
1.2	Steady rate of development of new drugs.....	13
1.3	Capital raised by biotechnology companies in North America and Europe per year.....	14
1.4	R&D stage agreements.....	15
1.5	Product licensing agreements.....	15
1.6	Joint venture activity, 2008 to October 2012..	16
1.7	Company type combinations involved in deal making, 2008 to 31 October 2012.....	16
1.8	Biotech-biotech deal making activity, 2008 to October 2012.....	17
1.9	Global-global company deal making activity, 2008 to October 2012.....	17
1.10	Number of deals, 2008 to October 2012.....	18
2.1	Number of all deals by phase of development for deals from 2001 to October 2012.....	20
2.2	Average total deal values and average upfront payments for deals by phase of development for deals from 2001 to October 2012.....	20
2.3	Capabilities across the R&D cycle.....	24
2.4	Key areas for relationship fit.....	26
2.5	The partner search.....	27
3.1	Contact sequence.....	34
7.1	Integrated valuation methods.....	67
7.2	Ideal benchmarking deal cluster.....	70
7.3	Non-ideal benchmarking deal cluster.....	70
7.4	Example pharmaceutical deal valuation force field.....	72
7.6	Pharmaceutical product decision tree.....	75
7.5	Attrition by phase and therapeutic area.....	75
7.7	The effect of time and risk on the value of deal components.....	77
9.1	The term of the working relationship.....	99
9.2	The negotiation team.....	101
9.3	Negotiation styles.....	104
10.1	Risks inherent in collaborations.....	108
10.2	The four phases of the alliance management life cycle.....	108
10.3	The roles of an alliance manager.....	111
10.4	Relationship between substantive conflict and interest.....	115

IMS HEALTH®

EUROPE & WORLDWIDE

210 Pentonville Road
London N1 9JY
United Kingdom
Tel: +44 (0)20 3075 5888

THE AMERICAS

IMS Health
200 Campus Drive
Collegeville, PA 19426
USA
Tel: +1 610 244-200

ASIA-PACIFIC

10 Hoe Chiang Road
Keppel Towers # 23-01/02
Singapore 089315
Tel: 65-6227-3006

JAPAN

Toranomon Towers Office 4-1-28
Toranomon, Minato-ku
Tokyo 105-0001
Japan
Tel: 81-3-5425-9000

For all office locations, visit: www.imshealth.com/locations

ABOUT IMS

IMS Health is the leading provider of information services for the healthcare industry around the world. The company draws on its global technology infrastructure and unique combination of in-depth, sophisticated analytics, on-shore and off-shore commercial services, and consulting platforms to help clients better understand the performance and value of medicines. With a presence in 100+ countries and more than 55 years of industry experience, IMS Health serves leading decision makers in healthcare, including pharmaceutical manufacturers and distributors, providers, payers, government agencies, policymakers, researchers and the financial community. Additional information is available at <http://www.imshealth.com>