BROCHURE: Option & Evaluation Agreements in Pharma and Biotech

- Trends in option and evaluation agreements
- Option and evaluation agreement structure
- Option and evaluation contract documents
- Option and evaluation agreement terms
- Top option and evaluation deals by value
- Most active option and evaluation dealmakers
- Bigpharma option and evaluation dealmaking activity

Publication date: June 2010
Report code: CP2059
Version: 2
Report description

The Option and Evaluation Agreements in Pharma and Biotech report provides comprehensive understanding and unprecedented access to the option and evaluation partnering agreements entered into by the world's leading biopharma companies.

This report provides details of the latest option and evaluation agreements announced in the pharmaceutical and biotechnology sectors. Detailed and comprehensive, the report provides details of option and evaluation agreements from 2003 to early 2010.

The report provides a detailed understand and analysis of how and why companies enter option and evaluation deals. The majority of deals are option agreements whereby one party to the agreement obtains an option right from the other party.

Understanding the flexibility of a prospective partner's negotiated deal terms provides critical insight into the negotiation process in terms of what you can expect to achieve during the negotiation of terms. Whilst many smaller companies will be seeking details of the payments clauses, the devil is in the detail in terms of how payments are triggered – contract documents provide this insight where press releases and databases do not.

This report contains over 750 links to online copies of actual option and evaluation contract documents as submitted to the Securities Exchange Commission by pharma/biotech companies and their partners.

Contract documents provide the answers to numerous questions about a prospective partner's flexibility on a wide range of important issues, many of which will have a significant impact on each party's ability to derive value from the deal.

The initial chapters of this report provide an orientation of option and evaluation dealmaking and business activities. Chapter 1 provides a brief introduction to the report, whilst chapter 2 provides an analysis of the trends in option and evaluation as well as a discussion on the merits of each type of deal.

Chapter 3 provides an overview of the structure of option and evaluation deals. The chapter includes numerous case studies to enable understanding of both option and evaluation deals where partnering or acquisition is the primary focus of the agreement.

Chapter 4 provides a review of the leading option and evaluation deals since 2000. Deals are listed by headline value and most active bigpharma. Where the deal has an agreement contract published at the SEC a link provides online access to the contract.

Chapter 5 provides a comprehensive listing of the top 50 bigpharma companies with a brief summary including option and evaluation frequency followed by a comprehensive listing of option and evaluation contract documents available in the public domain. Each deal title links via Weblink to an online version of the actual contract document, providing easy access to each contract document on demand.

Chapter 6 provides a comprehensive listing of all option and evaluation agreement contracts available in the public domain, respectively. The chapter is organized by A-Z company name, option/evaluation type, therapy area and stage of development at signing. Each deal title links via Weblink to an online version of the actual contract document, providing easy access to each contract document on demand.
Key benefits

Option and Evaluation Agreements in Pharma and Biotech provides the reader with the following key benefits:

- In-depth understanding of option and evaluation deal trends since 2000
- Analysis of the structure of option and evaluation agreements with numerous real life case studies
- Comprehensive access to over 750 actual option and evaluation contracts entered into by the world’s biopharma companies
- Detailed access to actual option and evaluation contracts entered into by the leading fifty bigpharma companies
- Insight into the terms included in a option and evaluation agreement, together with real world clause examples
- Understand the key deal terms companies have agreed in previous deals
- Undertake due diligence to assess suitability of your proposed deal terms for partner companies

Report scope

Option and Evaluation Agreements in Pharma and Biotech is intended to provide the reader with an in-depth understanding of the option and evaluation trends and structure of deals entered into by leading biopharma companies worldwide.

Option and Evaluation Agreements in Pharma and Biotech includes:

- Trends in option and evaluation dealmaking in the biopharma industry since 2000
- Analysis of option and evaluation deal structure
- Case studies of real-life option and evaluation deals
- Access to over 750 option and evaluation contract documents
- The leading option and evaluation deals by value since 2000
- Most active option and evaluation dealmakers since 2000
- The leading option and evaluation partnering resources

In Option and Evaluation Agreements in Pharma and Biotech, the available contracts are listed by:

- Company A-Z
- Headline value
- Option type
- Stage of development at signing
- Therapeutic area

Each deal title links via Weblink to an online version of the actual contract document, providing easy access to each contract document on demand.
The **Option and Evaluation Agreements in Pharma and Biotech** report provides comprehensive access to available contract documents for over 750 option and evaluation deals. Analyzing actual contract agreements allows assessment of the following:

- What are the precise option and evaluation rights granted?
- What is actually granted by the agreement to the partner company?
- What exclusivity is granted?
- What is the payment structure for the deal?
- How are sales and payments audited?
- What is the deal term?
- How are the key terms of the agreement defined?
- How are IPRs handled and owned?
- Who is responsible for commercialization?
- Who is responsible for development, supply, and manufacture?
- How is confidentiality and publication managed?
- How are disputes to be resolved?
- Under what conditions can the deal be terminated?
- What happens when there is a change of ownership?
- What sublicensing and subcontracting provisions have been agreed?
- Which boilerplate clauses does the company insist upon?
- Which boilerplate clauses appear to differ from partner to partner or deal type to deal type?
- Which jurisdiction does the company insist upon for agreement law?

**Number of pages:**

The report is comprised of 443 pages.
Executive Summary

Welcome to the Option and Evaluation Agreements in Pharma and Biotech report.

The report provides a detailed understand and analysis of how and why companies enter option and evaluation deals. The majority of deals are option agreements whereby one party to the agreement obtains an option right from the other party.

Detailed and comprehensive, the report provides details of option and evaluation agreements from 2003 to early 2010.

There are two major forms of deal term that allow a party to a deal to secure rights to an asset subject to a future event namely, option and evaluation.

Evaluation agreements allow a party to the deal to obtain rights to a technology or compound, subject to a period of time to evaluate the quality, scope and applicability of the technology to its intended endpoint. Normally the technology is at an early stage and/or unproven and the partnering company wishes to assess the technology as part of the due diligence process in advance of signing a long term licensing agreement.

Evaluation agreements have been a mainstay of technology licensing from the earliest days.

An option agreement differs in that the option is often an integral part of an agreement already entered by the parties, providing the party with the option right to retain or extend certain rights to the technology already partnered.

Option agreements are becoming increasingly popular as they create additional flexibility within a deal for additional rights that the parties do not wish to commit at the outset of the agreement.

A new form of option-based deal has emerged recently where the large company makes an payment to a smaller discovery stage company in return for an option to obtain a license to the technology at a defined milestone at an agreed point in the future. Such deals have become increasing popular as a means of smaller companies accessing much needed funding at a time when other more conventional sources have declined.

This report focuses on option and evaluation agreements and clauses within broader agreements between bigpharma-bigpharma, bigpharma – smaller company, and smaller company-smaller company, providing a detailed insight into all such deals.

This report provides an overview of option and evaluation agreements, the common clauses, rights and options in the agreement, and also a comprehensive review of deals signed in the last five years.

This report focuses on option and evaluation agreements between bigpharma-bigpharma, bigpharma – smaller company, and smaller company-smaller company, providing a detailed insight into all such deals.

This report contains over 400 links to online copies of actual option and evaluation contract documents as submitted to the Securities Exchange Commission by pharma/biotech companies and their partners.

Contract documents provide an important insight into how a prospective partner drafts and agrees key deal terms in a legal document.

Company contract agreements can be used to develop a more in-depth understanding of the prospective partner company’s agreement style and the types of clauses that a company accepts as part of a deal.
For example, analyzing actual company agreements allows assessment of the following:

- What are the precise option and evaluation terms agreed between the parties?
- What is actually being optioned by the licensee company?
- What is the payment structure for the option?
- What are conditions of option and evaluation?
- What are the rights of each party?
- How are the key terms of the agreement defined?
- How are IPRs handled and owned?
- Under what conditions can the deal be terminated?
- Which boilerplate clauses does the company insist upon?
- Which boilerplate clauses appear to differ from option to evaluation?
- Which jurisdiction does the company insist upon for agreement law?

The initial chapters of this report provide an orientation of option and evaluation dealmaking and business activities. Chapter 1 provides a brief introduction to the report, whilst chapter 2 provides an analysis of the trends in option and evaluation as well as a discussion on the merits of each type of deal.

Chapter 3 provides an overview of the structure of option and evaluation deals. The chapter includes numerous case studies to enable understanding of both option and evaluation deals where partnering or acquisition is the primary focus of the agreement.

Chapter 4 provides a review of the leading option and evaluation deals since 2000. Deals are listed by headline value and most active bigpharma. Where the deal has an agreement contract published at the SEC a link provides online access to the contract.

Chapter 5 provides a comprehensive listing of the top 50 bigpharma companies with a brief summary including option and evaluation frequency followed by a comprehensive listing of option and evaluation contract documents available in the public domain. Each deal title links via Weblink to an online version of the actual contract document, providing easy access to each contract document on demand.

Chapter 6 provides a comprehensive listing of all option and evaluation agreement contracts available in the public domain, respectively. The chapter is organized by A-Z company name, option/evaluation type, therapy area and stage of development at signing. Each deal title links via Weblink to an online version of the actual contract document, providing easy access to each contract document on demand.

The report also includes numerous tables and figures that illustrate the trends and activities in option and evaluation dealmaking since 2000.

In conclusion, this report provides everything a prospective dealmaker needs to know about option and evaluation deals by using actual contract documents and clauses to provide real-life analysis and insight.
Table of contents

Executive Summary

Chapter 1 – Introduction

Chapter 2 – Trends in option and evaluation dealmaking

2.1. Introduction
2.2. Difference between option and evaluation deals
2.2.1. Types of option agreement
2.3. Trends in option/evaluation deals since 2000
2.4. Option-based deals
2.4.1. Attributes of option-based deals
2.4.2. Reasons for entering an option-based deal
2.4.3. Uptake of option exercise
2.4.4. The future of option-based deals
2.5. Co-promotion options
2.5.1. Attributes of co-promotion in multi-component deals
2.5.2. Reasons for including co-promotion options in a deal
2.5.3. Uptake of co-promotion rights
2.5.4. Co-promotion rights as bargaining chips
2.5.5. The future of co-promotion as part of multicomponent deals
2.6. Company acquisition options
2.6.3. The future of option to acquire deals

Chapter 3 – Overview of option and evaluation deal structure

3.1. Introduction
3.2. Evaluation agreement structure
3.2.1. Example evaluation agreements
3.3. Option agreement structure
3.3.1. Example option agreements
3.3.1.a. Option to license
Case study 4: GlaxoSmithKline – Regulus Therapeutics – April 2008
3.3.1.b. Option to extend/expand applications/territories
Case study 5: Salix – Dr Falk – April 2007
3.3.1.c. Option to finance
Case study 6: Merck KgaA – Archemix – June 2007
3.3.1.d. Option to co-promote
Case study 7: Novartis – Anadys – June 2005
3.3.1.e. Option to manufacture/supply
Case study 8: NPS Allelix – Nycomed – July 2007
3.4. Option to acquire agreement structure
3.4.1. Example acquisition option clauses
3.4.1.a. Case study 9: MGI Pharma – AkaRx – October 2007

Chapter 4 – Leading option and evaluation deals

4.1. Introduction
4.2. Top partnering deals incorporated an option clause by value
4.3. Bigpharma option deal activity
Chapter 5 – Bigpharma option and evaluation agreements

5.1. Introduction
5.2. How to use option/evaluation agreements
5.3. Company option and evaluation agreement listings
  Abbott
  Actavis
  Alcon Labs
  Allergan
  Amgen
  Astellas
  AstraZeneca
  Baxter International
  Bayer
  Biogen Idec
  Boehringer Ingelheim
  Bristol-Myers Squibb
  Cephalon
  Chugai
  CSL
  Daiichi Sankyo
  Dainippon Sumitomo
  Eisai
  Eli Lilly
  Forest Laboratories
  Genentech
  Genzyme
  Gilead Sciences
  GlaxoSmithKline
  Hospira
  Johnson & Johnson
  Lundbeck
  Menarini
  Merck & Co
  Merck Serono
  Mitsubishi Tanabe
  Mundipharma
  Novartis
  Novo Nordisk
  Nycomed Pharma
  Otsuka
  Pfizer
  Procter & Gamble
  Ratiopharma
  Roche
  Sanofi-Aventis
  Schering Plough
  Servier
  Shire
  Solvay
  Takeda
  Teva
  UCB
  Watson
  Wyeth
Chapter 6 – Option and evaluation agreement directory 2003 to early 2010

6.1. Introduction
6.2. Company A-Z
6.3. Deals by type
   Acquisition
   Co-development
   Co-marketing
   Co-promotion
   Evaluation
   Extension
   Financing
   Licensing
   Marketing
   Supply
6.4. Deals by stage
   Discovery
   Preclinic
   Phase I
   Phase II
   Phase III
   Regulatory
   Marketed
   Formulation
6.2. Deals by therapy
   Cardiovascular
   Central Nervous System
   Dermatology
   Gastrointestinal
   Genitourinary
   Hematology
   Hormonal
   Immunology
   Infection
   Inflammation
   Metabolic
   Musculoskeletal
   Oncology
   Ophthalmic
   Respiratory
   Delivery

Appendices
   Appendix 1 – Option/evaluation references
   Appendix 2 – Resources
   Appendix 3 – Deal type definitions
   Appendix 4 – Example M&A option contract document
   Appendix 5 - Example option partnering contract document
   About CurrentPartnering
TABLE OF FIGURES

Figure 1: Definition of option and evaluation
Figure 2: Types of option right
Figure 3: Trends in option/evaluation deal announcements, 2000-2009
Figure 4: Option/evaluation deals signed at each phase of development, 2000-2009
Figure 5: Recent option-based deals
Figure 6: Example deals where co-promotion options have been actively exercised, since 2000
Figure 7: Recent ‘option to acquire’ deals
Figure 8: Components of the evaluation deal structure
Figure 9: Types of option in an agreement
Figure 10: Attributes of option terms:
Figure 11: Top 25 partnering deals incorporating an option/evaluation clause by value since 2000
Figure 12: Bigpharma – top 50 – option deals since 2003
Figure 13: Online partnering resources
Figure 14: Deal type definitions
Figure 15: Option for M&A agreement between Abbott Molecular – Isis Pharmaceuticals – Ibis Biosciences – January 2005
Figure 16: Option in partnering agreement between Array Biopharma – Celgene – September 2007
CurrentPartnering Reports Order Form
Option & Evaluation Agreements in Pharma and Biotech

Complete this form then fax, mail, or email to order this report

2Market Information, Inc.
1992 Westminster Way
Atlanta, GA 30307 USA
Phone: (877) 729-0959 or (239) 263-0605
Fax: (404) 381-1354
Email: info@technologytransfertactics.com

Name: ____________________________________________________________
Title: __________________________________________________________________________
Company: __________________________________________________________________________
Address: __________________________________________________________________________
City: __________________________ State: _________  Zip: ____________
Country: __________________________________________________________________________
E-Mail required: ____________________________________________
Phone: ___________________________ Fax: __________________________

Please choose from the following options:
☐ $2,495 -- PDF Format  or  ☐ $7,495 -- Site License
  ☐ PDF on a CD-Rom – add: $500
  ☐ print version –add: $500

Payment options:
☐ Check enclosed  ☐ Bill me  ☐ P.O. # ______________
☐ Charge my credit card
  ☐ Visa  ☐ MC  ☐ AMEX  ☐ DISC
Account # ____________________________ Exp: ________ CVV*: ___________
Signature: __________________________________________________________________________

* The 3-4 digit code on the back of your credit card

Source: WEB