

## Key Findings

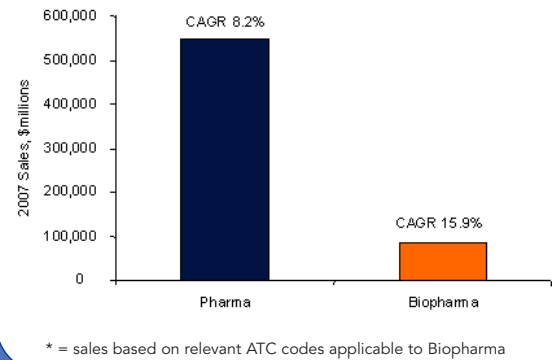
**Several top-ranked Biopharma companies have matched the consistent sales growth of major traditional pharma companies.** A key component of this success has been the increasing reliance of big Pharma to improve R&D productivity and rejuvenate sales of marketed portfolios through licensing and partnership deals.

**Big Pharma has been acquiring Biopharma companies at an increasing rate, resulting in this becoming the fastest-growing M&A sector in 2008** with deal values up 87%. Intense competition and financial uncertainty has also prompted a surge in biopharma consolidation, with 52 biopharma/biopharma deals in 2007.

**Considerable potential for Biopharma licensing deals still exists,** particularly within the OAD class of drugs and non-invasive insulin drug delivery technologies.

**The total deal size of early-stage alliances with biopharma has increased six-fold, with total deal values in 2007 estimated at \$18bn.** This has been driven by the relatively lower costs of discovery and lead development, despite the higher risk of failure.

**Co-development/co-promotion deals accounted for 30% of licensing deals over 2006-07.** Licensing deals will continue to become more complex due to biopharma's desire to remain involved in their product lifecycle beyond the stages of discovery and development



**Figure 1.4: Biopharma vs. Pharma global sales\***

"While Pharma sector sales accounted for 86.5% or \$548,790m of the global market share in 2007, Biopharma sales grew at a stronger rate than Pharma's over 2006-07: 15.5% compared to 8.6%. Similarly, Biopharma grew at an impressive CAGR of 15.9% over 2003-07, compared to the 8.2% CAGR of the Pharma industry."

## Use this report to...

- **Examine the licensing landscape of the biopharma industry** with this report's analysis of Biopharma and Pharma licensing and alliance activity and an examination of specific approaches utilized by both sectors.
- **Discover the drivers and challenges facing Biopharma licensing,** understand how Biopharma companies are preparing to exploit new opportunities and assess deal-making trends across clinical trials phases and key therapeutic areas.
- **Evaluate the strategies of leading companies involved in biopharmaceutical licensing** with this report's analysis of deal activities amongst leading players and identify the changing dynamics of Biopharma/Pharma partnerships.
- **Assess the future prospects of the Biopharma industry** and how current market and political/regulatory factors will impact the dynamics of licensing and alliances, as well as potential strategies for sustaining growth.

## Explore issues including...



### Biopharmas reduced reliance on Pharma.

Biopharma is sustaining its efforts to increase its role outside of product development/discovery to become actively engaged in the future of their products. As such, it is becoming increasingly difficult to differentiate big Pharma from major Biopharma companies.



### Optimizing revenue potential.

Biopharma are increasingly targeting high value therapy areas, such as oncology and inflammatory disease, bringing them into direct competition with major Pharma.



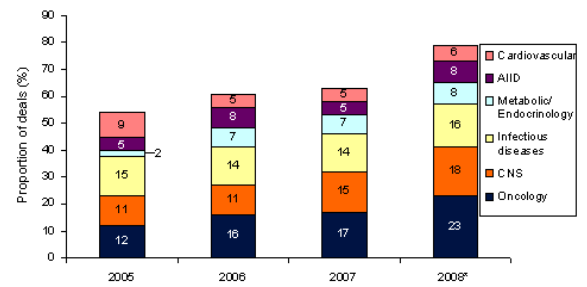
### Future competitive strategies.

With licensing deals increasing in value and complexity, Biopharma companies are looking to increase their involvement by forming long-term, partnership-based relationships. This active engagement in licensing deals will typically involve the negotiation of equity investment and the co-promotion and co-marketing of a drug that allows Biopharma to generate additional downstream revenues.



### Drug development potential.

The emergence of several new Biopharma companies with innovative technology platforms has created immense potential for intra-Biopharma licensing trends to continue developing novel drugs that can successfully differentiate themselves within the marketplace.



**Figure 2.14: Therapeutic focus in Biopharma licensing deals, 2005–08**

As of October 2008, oncology was the primary therapy area being targeted in licensing deals involving Biopharma, accounting for 23% of deals in 2008. This trend looks set to continue in the short term, with the oncology market forecast to expand by a CAGR of 5.1% to 2013.

## Discover...

- How will the increasing competition for attractive Biopharma licensing candidates affect deal terms and values?
- How can Biopharma companies improve their licensing strategies to ensure future growth?
- What have been the major trends in licensing agreements between Biopharma and Pharma over 2001-08?
- Which strategies have Biopharma used to reduce their reliance on Pharma?
- How has the value, volume and competition for Biopharma licensing deals changed over 2001-08?
- What have been the strategies of successful Biopharma and Pharma deal-makers?
- Why are Biopharma and Pharma increasingly adopting M&A strategies instead of entering into licensing agreements?

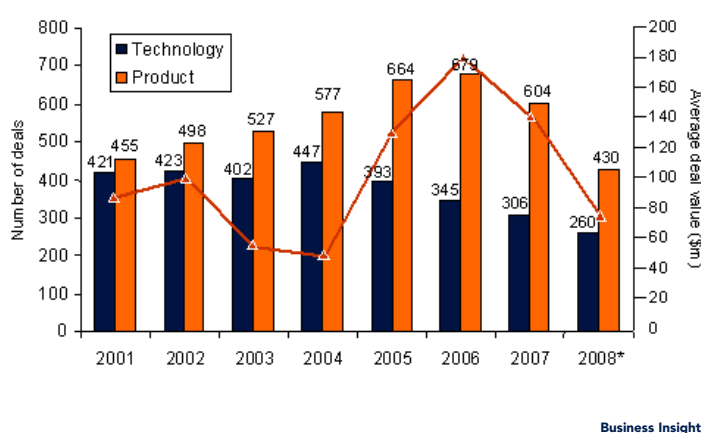
## Sample Information

### Chapter 2: Biopharmaceutical deals and trends

#### Number and average value of Biopharma Licensing Deals

Biopharma licensing peaked in 2005 with 1,057 deals, largely attributable to the height of licensing activity with leading pharmaceutical companies and an increase in the number of deals with other Biopharma companies. The number of licensing deals involving Biopharma has fallen over 2007–08, which is believed to be indicative of the evolving ability of Biopharma to independently develop and bring drugs to market. The escalation of M&A, an increasing trend since 2004, has also impacted the level of Biopharma licensing deals. Over the past three years, on average, there have been more than 15 M&As per year between Pharma and Biopharma, along with an estimated 52 Biopharma/Biopharma consolidation deals in 2007 alone. This internal Biopharma consolidation emerges as a definitive indication of the ability of well-established Biopharma companies to compete strongly with traditional Big Pharma, which has been driven by their robust pipelines and development capabilities.

**Figure 2.5: Number and average value of Biopharma licensing deals, 2001–08**



Deals involving the exchange of technology and scientific knowledge remain a crucial component in licensing deals and alliances between the Pharma and Biopharma industries. As compared to straight licensing deals, these technology-based deals have the potential to offer significant access to the discovery and development of a number of compounds. The increasing emergence of biologic technology deals has surpassed the number of drug discovery deals for small-molecule technologies over the period of analysis, which is further discussed below.

The average deal values for Biopharma companies, mirroring the activity of licensing deals, experienced consistent growth over 2004–06, peaking at an average of \$175m in 2006. Despite the declining trend in licensing deals and value, there still exists an opportunity for growth within the Biopharma industry, which is forecast to be driven by smaller and emerging Biopharma companies.

#### Licensing deal partners

The trends for the top 20 Biopharma companies (Abraxis, Actelion, Amgen, Amylin, Biogen-Idec, Celgene, Cephalon, CSL, Cubist, Genentech, Genzyme, Gilead, Imclone, Merck KGaA/Serono, MedImmune, MGI, Millennium, PDL BioPharma, UCB and Viropharma) are based on 2007 revenues. The licensing activity of these Biopharma companies has shown a split between deals with Pharma and Biopharma, with consistently more deals with other Biopharma companies since 2004. While relying on Pharma for deals, Biopharma has increasingly looked within the biopharma industry to maintain revenues through licensing deals and alliances.

## Table of Contents

### CHAPTER 1: INTRODUCTION TO BIOPHARMACEUTICALS AND LICENSING

- Introduction
- Overview of the biopharmaceutical industry
  - The Biopharma-Pharma relationship
- The licensing process
  - Meeting the licensing challenge
- Biopharma continues to shine

### CHAPTER 2: BIOPHARMACEUTICAL DEALS AND TRENDS

- Introduction
- Biopharmaceutical licensing trends
  - Number and average value of Biopharma licensing deals
  - Licensing deal partners
  - Biopharma's standing: out-licensing versus in-licensing deals
  - Licensing deal types
  - Licensing trends in drug development
  - The rising costs of early-stage licensing
  - Mid-stage deal-making: lucrative prospects
  - Therapeutic focus in Biopharma licensing

### CHAPTER 3: DRIVERS AND RESISTORS OF BIOPHARMACEUTICAL LICENSING

- Introduction

- Overview of drivers and resisters in biopharmaceutical licensing
  - Key drivers
    - Generating cash
  - Pharma turns to Biopharma to maintain revenue growth; Biopharma gaining an upper hand
    - Risk sharing
    - Access to expertise
    - Key resisters
    - Reduced control
    - Increasing complexity of licensing deals: positive for Biopharma but with a higher risk attached
  - Stricter regulatory and political environments
  - Future strategic direction

### CHAPTER 4: LEADING COMPANIES INVOLVED IN BIOPHARMACEUTICAL LICENSING

- Introduction
- Who is looking to Biopharma and why?
  - Two sides of the Pharma coin: GlaxoSmithKline and Roche
  - GlaxoSmithKline: a Biopharma façade?
  - Roche: building upon an established presence in Biopharma
- The Biopharma/Pharma dynamic
  - Amgen: the leading Biopharma
  - Gilead: diversification after market domination
  - Cephalon: a Biopharma out-licensor

- Alynlam: a developer of novel therapeutics based on RNA interference

### CHAPTER 5: THE EVOLUTIONARY PATTERN OF BIOPHARMACEUTICAL LICENSING

- Introduction
- The big deals of 2008: a sign of what is to come?
  - Who holds the future to ImClone?
  - The Roche and Genentech saga
  - Biopharma to Biopharma: Genzyme and Isis
  - Takeda looks to Biopharma for entry to the US market
  - Pfizer and Wyeth
  - Are M&As the new licensing?
  - Potential arrival of biosimilars: a catalyst for Biopharma M&A
- The financial crisis and the future of Biopharma
- The promise of emerging markets
- Keys to future success
  - Recommendations and strategies for future Biopharma licensing deals and alliances

## Table of Contents

### LIST OF FIGURES

- Number of NMEs and BLAs approved by the US FDA
- Strengths of Biopharma and Pharma
- Overview of the pharmaceutical licensing process
- Global sales\* of Biopharma vs. Pharma
- Number and average value of Biopharma licensing deals, 2001–08
- Number of top 20 Biopharma licensing deals by partner, 2001–08
- Number of Biopharma in- and out-licensing deals by partner, 2004–08
- Biopharma licensing by deal type, 2001–08
- Biopharma out-licensing distribution by clinical stage, 2001–08
- Early-stage deal models with associated pros & cons
- Early-stage alliances—number of deals and deal size, 2001–08
- Trends in technology, Biopharma out-licensing, 2002–07
- Number of Biopharma out-licensing deals (\$100m+ nominal deal value) by clinical stage, 2005–08
- Therapeutic focus in Biopharma licensing deals, 2005–08
- Drivers and resistors facing biopharmaceutical licensing
- Biopharma R&D spend

- Biopharma funding
- Progression of Biopharma's involvement in licensing deals
- Estimated last patent expiry dates of selected proteins
- Future strategic directions for Biopharma in meeting current challenges
- Biopharma's transition via forward and downward integration
- Announced number of Biopharma mergers & acquisitions, 2001–08
- Drug patent expiries in the US, 2008-2012
- Future licensing and alliance scenarios for Biopharma

### LIST OF TABLES

- GSK's licensing and alliance activity, 2008
- GSK's licensing and alliance activity, 2007
- GSK's licensing and alliance activity, 2006
- GSK's licensing and alliance activity, 2005
- Roche's licensing and alliance activity, 2008
- Roche's licensing and alliance activity, 2007
- Roche's licensing and alliance activity, 2006
- Roche's licensing and alliance activity, 2005
- Amgen's licensing and alliance activity, 2007–08
- Amgen's licensing and alliance activity, 2005–06
- Gilead's licensing and alliance activity, 2005–07
- Cephalon's licensing and alliance activity, 2005–07
- Alnylam's licensing and alliance activity, 2005–07
- Sales in 7MM and pharmerging markets (\$m), 2003-07