Marketspace

Trends underlying early-stage drug discovery and development collaborations from October 2002 to September 2004

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Abstract

As part of Datamonitor's alliance and licensing strategic analysis, the authors have completed a two year survey of the trends underlying early-stage drug discovery and development collaborations between October 2002 and September 2004, which included 524 early-stage deals. Deal analysis shows that the leading pharma and biotech companies (fully integrated players) are the principal collaboration seekers, and that target and product innovation is driving the new wave of 21st century deals. These deals cover all phases of early-stage drug development, with lead product/target identification/validation accounting for the greatest proportion of collaborations. This represents a shift away from initial-stage collaborations, which are primarily focused on technologies such as genomics, as a result of the lack of tangible results that such technologies have delivered in the past. Following the continuously increasing demand for late-stage high-value products, the aim of the money and time invested in these early-stage collaborations is to reverse the pipeline productivity crisis currently affecting the industry's leaders over the mid to long term.

Keywords: *early-stage collaboration, licensing, lead optimisation, lead identification, target validation, drug discovery*

INTRODUCTION

There is currently a crisis among the pharmaceutical industry as in-house organic R&D fails to generate a significant number of high-value products to drive company growth and replace sales generated by products approaching the end of their life cycle that are facing patent expiry and generic competition. Early-stage collaborations within the biopharma sector are vital in driving innovation evolution through therapeutic and technological diversification.

Overall, early-stage deals can generally be split into licensing and co-research and development deals. Alliance seekers/licensees are looking to increase their exposure to novel technologies, drive up target and lead identification and boost early-stage drug development. In return, their collaboration partners/licensors are set to gain greater financial stability, validate their technology and accelerate product development and optimisation.

With the industry shifting as a whole towards utilising licensing to solve poor in-house R&D productivity, high-value licensing deal targets are becoming increasingly expensive and difficult to locate. An alternative for these companies is therefore to enter into co-R&D collaborations with promising emerging biopharmaceutical companies, to gain

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exposure to a novel technology platform, target or product.

Datamonitor's strategic analysis unit has analysed 524 early-stage collaborations initiated within the global biopharmaceutical sector for the two year period between October 2002 and September 2004. Key alliance trends have been extracted, providing information on collaboration focus, product class, alliance seeker class, deal type, therapeutic focus and geographical focus.

COLLABORATION FOCUS

The 524 early-stage collaborations were split into four major types, according to stage of evolution and breadth of focus, as shown in Figure 1. Together, these collaboration types make up the core drug discovery and early-stage drug development process.

Of the core drug discovery collaborations, initial-stage deals involve technologies such as genomics and biomarker studies. This stage is followed by lead and/or target identification and/or validation deals, then the more advanced lead identification and optimisation deals, which lead into the most advanced deal type examined, lead optimisation and further development.

Although these four deal types make up the core drug discovery path, there are also supplementary collaboration types that kick in at differing stages of this path, which aid the process. Examples of such deals include IT-focused collaborations (eg data handling and drug interaction modelling), ADMET (Adsorption, Distribution, Metabolism, Excretion and Toxicity)-focused collaborations and drug delivery collaborations.

The split by deal focus of the 524 identified early-stage collaborations has been summed by quarter to identify the centre of high alliance formation activity, as shown in Figure 2. Lead product and/or target identification and/or validation collaborations are the most common, as shown when all deals are summed in Figure 3.

COLLABORATION TYPE SPLIT BY PRODUCT CLASS, ALLIANCE SEEKER CLASS AND DEAL TYPE

In addition to dividing collaborations by focus, there are additional methods of deal categorisation. These include examining deal type by product type, deal type and type of alliance seeker/licensee, as shown in Figure 4. As shown in Figure 4(A), the

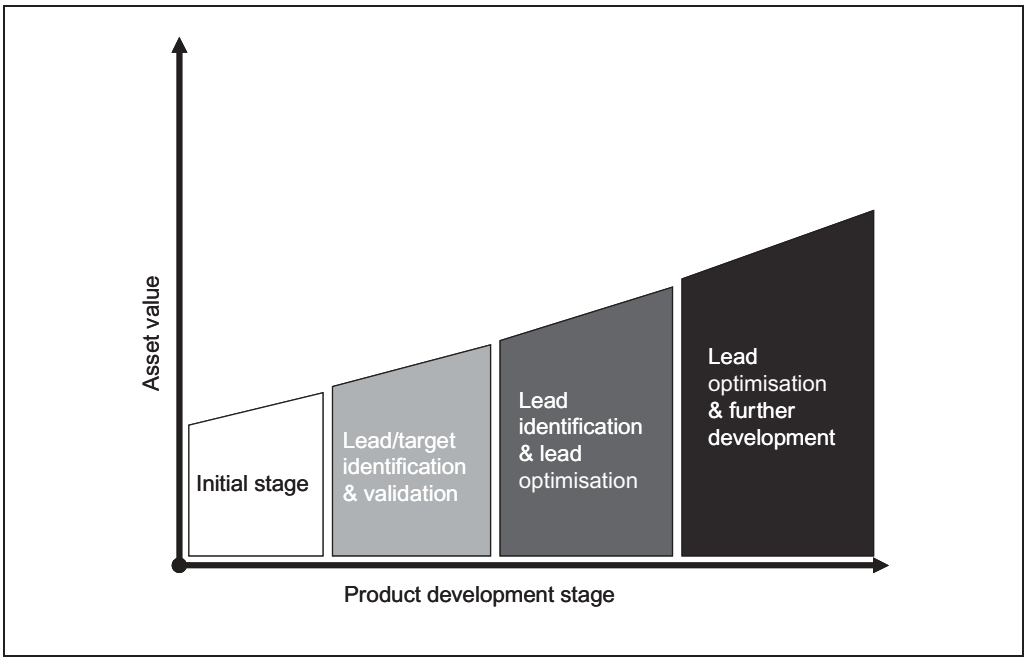

Figure 1: The four types of early-stage alliances identified by Datamonitor's strategic analysis
Source: Datamonitor

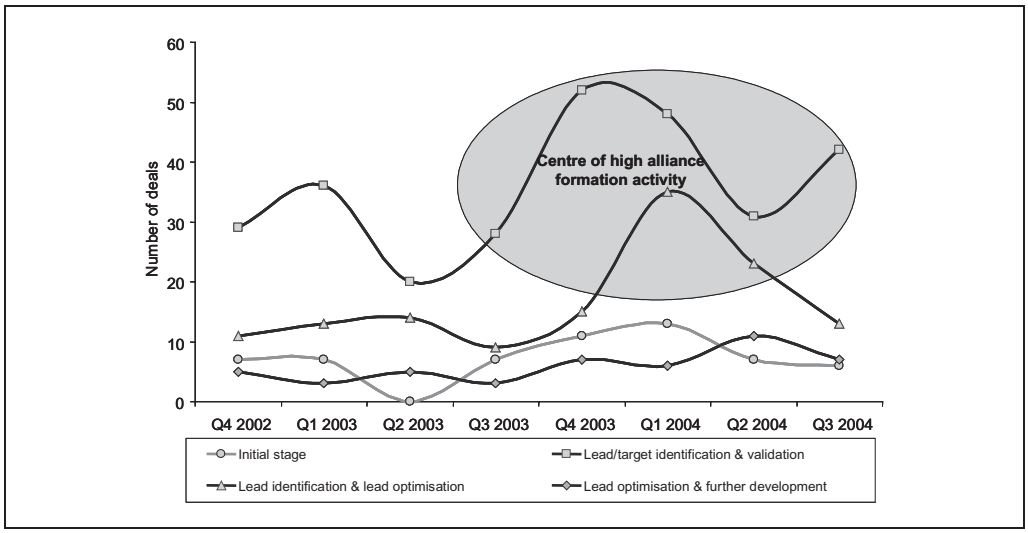

Figure 2: Early-stage collaboration and deal focus, split by quarter
Source: Datamonitor

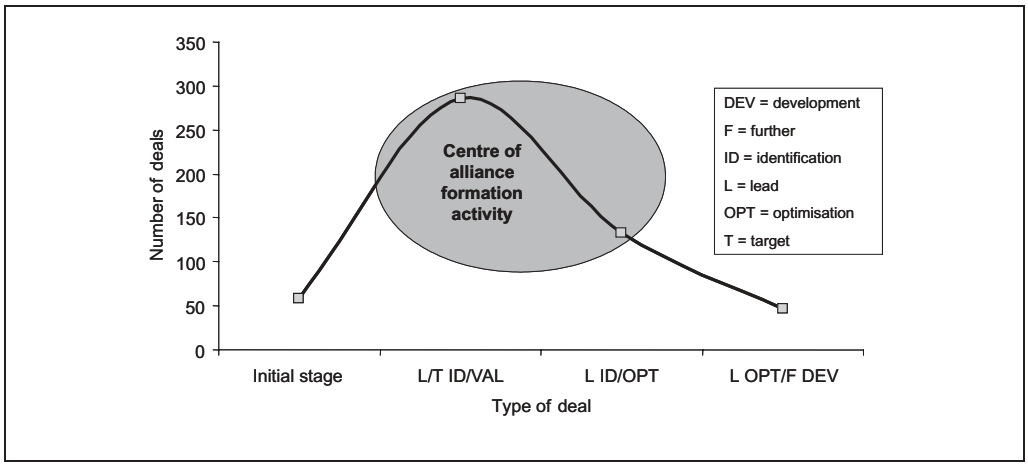

Figure 3: Early-stage collaboration and deal focus, summed
Source: Datamonitor

majority of collaborations (42 per cent) are not defined as small molecule or biologicals programs, owing to the early-stage nature of the collaborations examined. However, of those that are defined, both small molecule and biologicals programmes are well represented, although there is a bias towards small molecule programmes (35 versus 23 per cent).

Early-stage collaborations can also be divided into vertical and horizontal deal structure. Horizontal deals tend to be biased towards increasing exposure to a certain technology, while vertical deal types involve a greater degree of integration, with both collaboration partners involved for a greater proportion of the product development process. As shown in Figure 4(B), there is an approximately equal proportion of vertical deals (52 per cent) to horizontal deals (48 per cent).

Lastly, deals can be examined by the type of collaborators involved. The alliance seekers/licensees are split into fully integrated pharmaceutical companies (FIPCOs; eg Pfizer), fully-integrated biotech companies (FIBios; eg Amgen) and companies that do not fall into either of these categories (non-fully integrated Pharma/Biotechs, or NFIPBs). Because of the crisis in in-house R&D productivity among FIPCOs, these companies make up the majority (60 per cent) of the companies seeking collaborations, as shown in Figure 4(C). The collaboration partners/licensors for the majority of these

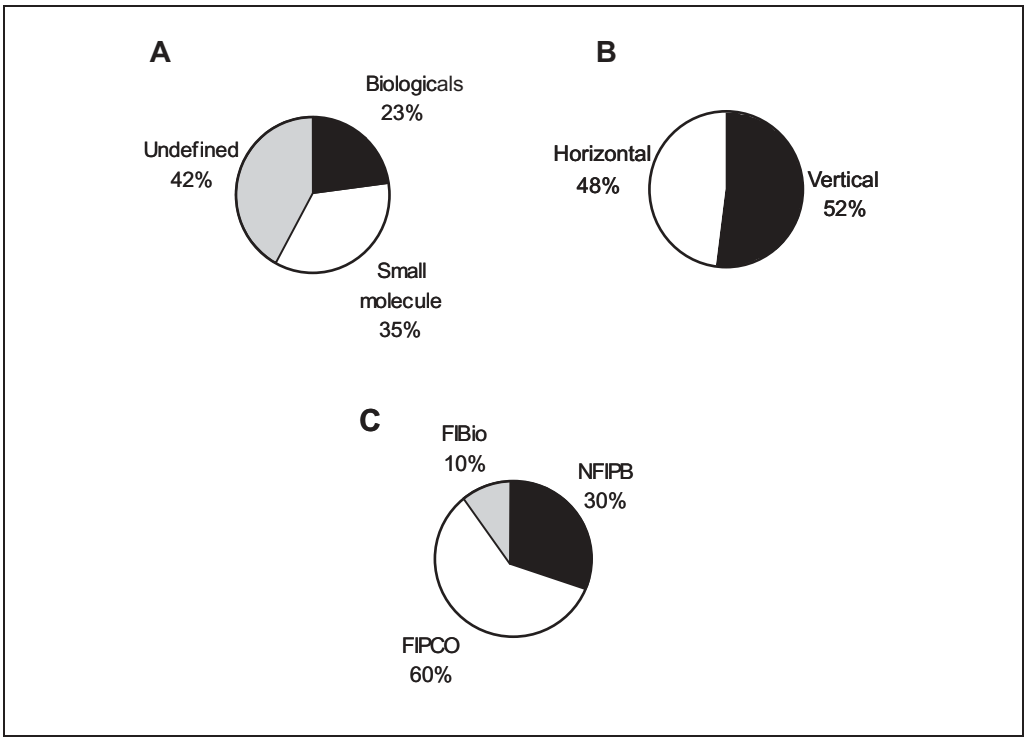

Figure 4: Early-stage collaborations, split by product class (A), deal type (B), and alliance seeker class (C)
Source: Datamonitor

deals are emerging biopharma companies that provide technology, products or targets.

COLLABORATION TYPE SPLIT BY THERAPEUTIC FOCUS AND BY GEOGRAPHICAL FOCUS

Early-stage collaborations can also be split by therapeutic focus and geographical focus. Owing to the early-stage nature of the collaborations examined, many of the 524 collaborations do not have a therapeutic focus (54 per cent). However, of those that do, the leading indication is oncology, as shown in Figure 5. This is one of the most competitive therapeutic areas, since oncology products are very attractive to large pharmaceutical companies, based on the forecast high market growth and the high levels of unmet need. Indeed, Datamonitor estimates that approximately one in five of all licensing deals are focused on oncology. Additional early-stage collaborations are themed towards four other key therapeutic areas – infectious disease, AIID (arthritis, immune and inflammatory diseases), CNS (central nervous system) and cardiovascular, which are similarly high-demand areas.

Collaborations examined were originated primarily by North American companies, for both alliance seekers/licensees (55 per cent of all collaborations) and alliance providers/licensors (63 per cent of all collaborations), as shown in Figure 6. This is related to the fact that the greatest number of FIPCOs is in the USA, as well as the strong investment climate for emerging biopharmaceutical companies in terms of both governmental funding and venture capital, respectively. Behind North America, European companies were the most active in early-stage collaboration formation.

Although the majority (57 per cent) of these collaborations were formed between companies operating in the same geographical region, a significant number (43 per cent) were formed between companies in different geographical categories, indicating that licensing and co-R&D sourcing is becoming increasingly internationalised in scope.

CONCLUSION

The R&D productivity crisis in the biopharma industry is driving significant

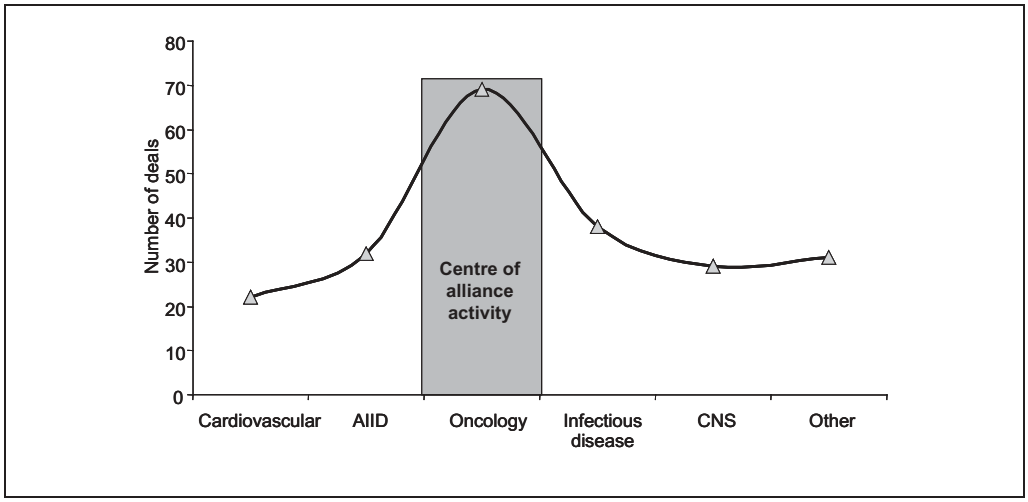

Figure 5: Early-stage collaboration type split by therapeutic focus
Source: Datamonitor

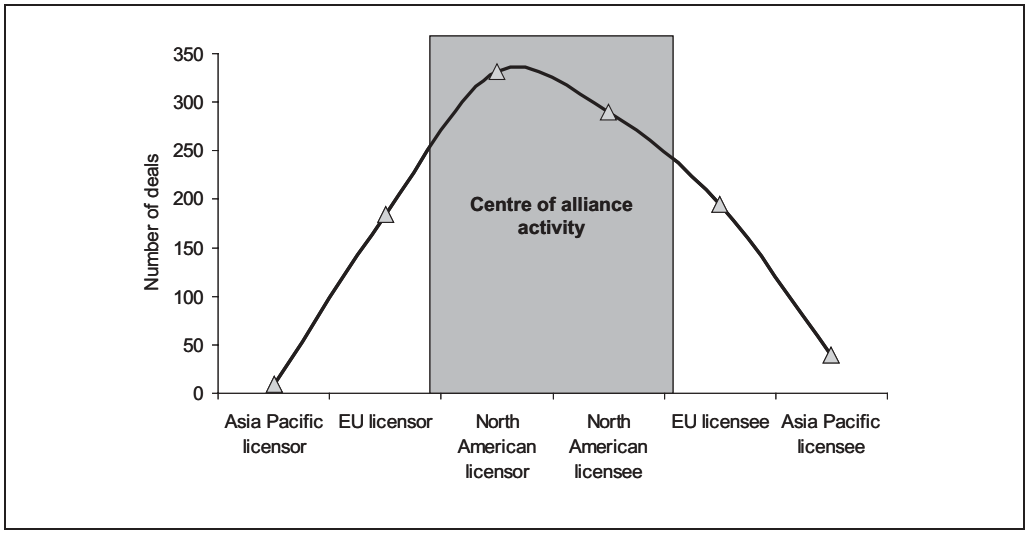

Figure 6: Early-stage collaboration type split by geographical region
Source: Datamonitor

licensing and co-R&D collaboration activity. Strong demand and the associated high price of high-value late-stage deals has led to a knock-on increase in early-stage collaborations, with 70 per cent of these collaborations now sourced by FIPCOs/FIBios. A wide range of early-stage collaborations have been formed over the two year period studied, with deals representing all levels of early-stage collaboration evolution. Lead product and/or target identification and/or validation deals are the most popular, followed by more advanced lead identification and optimisation deals and, together, these collaborations account for 80 per cent of the four deal types. This focus represents a shift away from very early-stage deals involving technologies such as genomics because of the lack of tangible results that such technologies have delivered. Vertical collaborations involving a greater degree of participation in the total drug development process are approximately as common as horizontal technology-focused deals. Collaborations are increasingly internationalised in scope and alliance seekers are interested in both small molecule and biologicals-focused deals, while oncology represents the most common therapeutic focus. The diversity of these collaboration types indicates the significant amount of time invested to identify high-value early-stage deals, which is set to increase innovation and reverse the pipeline productivity crisis.