

Throughout the pharmaceutical industry, there is continued concern over the increasing costs and diminishing returns of R&D and the declining number of new molecular entities being granted approval every year. To overcome these persistent challenges, many companies are adapting their business models accordingly. Although the mechanics of these organisational shifts are different within each business, they share – almost without exception – a growing emphasis on deal-making and partnerships.

Despite tightening regulatory environments and a cooling of investor confidence in the pharmaceutical industry (particularly in the EU), the life sciences sector continues to experience strong annual increases in raised capital. Strategic partnerships and licensing deals are the keys to this growth, with deal values totalling more than \$8.3 billion in the first half of 2006, compared with \$6.2 billion over the period in 2005.¹ An increasing

number of these deals have also been geared towards the establishment of enduring partnerships, which often involve more than one compound or technology.

Moving away from simple one-off deals towards long-term strategic partnerships is now a fundamental part of many business models. Moreover, this change in corporate mindset can be seen not only among the more mobile biotechs, but also across all levels of the industry. Recent examples among top-tier pharmaceutical giants include the success of Roche Pharma Partnering and Johnson & Johnson Pharmaceutical R&D group of companies. Although the two models are markedly different – with Roche seeking a large number of outside partnerships and J&J leveraging the strengths of the smaller, fast-moving partners predominantly under its umbrella – they both highlight the willingness of larger players to work with long-term collaborative programmes.

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KEY FACTORS FOR AN EFFECTIVE PARTNERSHIP

- Field specialisation
- Secure revenue
- Commercial and legal expertise
- Balanced risk

FUNDING THROUGH PARTNERSHIPS

By adding value through strategic partnerships, new business models are changing the way the industry prioritises licensing and collaboration. **Louise Makin**, CEO of BTG, explores this strategy and explains how it has helped accelerate the development of BTG's compounds.



One of the most successful illustrations of a partnership-based business model is drug development company BTG. Focused primarily on the fields of oncology and neuroscience, the company provides a powerful case study of many of the prerequisites that small- and medium-sized life sciences companies need to successfully build a profitable, sustainable and value creating business in drug development.

The BTG model

Originally set up by the UK Government to commercialise inventions resulting from publicly funded research, BTG was involved in both the physical and life sciences sectors. In 2004, new management brought the company through a strategic review, which concluded it should concentrate on the life sciences – developing and commercialising new drugs principally in the areas of neuroscience and oncology – and exit its activities in the physical sciences areas.

With the number and value of licensing agreements increasing annually, pharma and biotech partnering remains a great concern.

The company specialises in drug development through collaboration with a global network of corporations, research institutes and academic partners. It in-licenses early-stage drug programmes from pharmaceutical, biotech and academic sources and, using its in-house expertise, is able to add significant value to these compounds, taking them through preclinical and clinical development before out-licensing at the point where returns will be greatest. For some compounds, this will mean out-licensing (usually to a pharma company) at phase 2, but for other programmes, such as the company's lead agent for varicose veins, Varisolve®, BTG will take candidates through later-stage trials itself.

The monoclonal antibody drug Campath® (alemtuzumab) is a case in point. It originated from Cambridge University, UK, and the Medical Research Council, UK. BTG out-licensed the compound to LeukoSite in 1997 and the rights have since been passed via Ilex to Genzyme. The product is available for the third-line treatment of chronic lymphocytic leukaemia (CLL), and Genzyme is investigating it in clinical trials as a first-line therapy for CLL, as well as for the treatment of multiple sclerosis.

BTG also works with partners to in-license potential breakthrough treatments. Its phase 1 candidate for Alzheimer's disease, BGC20-1259, was acquired from Sankyo along with a group of CNS drug candidates when the Japanese firm took a strategic decision to leave neuroscience in 2004. Now BTG is moving the compound rapidly through early development, with phase 2 trials due to start in the second half of 2007.

In terms of scale, BTG is a lean organisation, possessing no dedicated R&D facilities. Instead, the company manages drug development through a mix of internal and external resources, including contract research organisations. This virtual drug development model employs many of the key differentiators and organisational skill sets required by small and medium-sized life science companies to establish and maintain more effective partnerships. For BTG, the most important of these features are:

- *Focus on two therapeutic areas.* Almost all of BTG's pipeline of compounds are drugs in the fields of oncology and neuroscience, indications with substantial market potential and unmet needs.
- *Secure revenue history.* Given the current industry climate, companies need to be confident that their potential long-term partners possess the financial stability to devote sufficient resources to suit the needs of their particular projects over a period of years. Unlike some other partnership-based companies that have defined themselves as virtual businesses, BTG generates ongoing revenue streams from royalties on licensed life sciences assets. The majority of these revenues are recycled back into the company's development programmes, ensuring the health of current collaborations and building value in its drug development programmes.
- *Commercial and legal expertise.* In deal-making, contract management, patent protection and risk evaluation.
- *Balanced risk.* While the majority of BTG's development programmes comprise novel drugs for oncology or neuroscience indications, its pipeline also includes a number of lower-risk, repositioned drug candidates, such as BGC20-0166, a combination of two known and approved drugs that is in BTG's proof-of-concept studies for the treatment of sleep apnoea.

Leading the trend

With both the number and value of licensing agreements across life sciences increasing annually, pharma and biotech partnering clearly remains a great concern. As activity in this sector continues to heat up, companies will increasingly look for partners with proven track records that can deliver greater value to their products, while offering flexibility in terms of project end-points.

Companies such as BTG have the expertise to develop early-stage compounds and offer de-risked assets for out-licensing. They do this by pulling together a network of drug development resources supported by a strong financial position. Such companies are in a better position to find the most effective development route for each individual candidate, ensuring faster progression to subsequent phases of development and, ultimately, the delivery of novel, safe and effective therapies. **END**

Reference

1 Garcia, S. 'Life sciences strategic deal-making trends'. *Genetic Engineering News*. 27 October 2006.