COMMERCIALIZATION — Decisions, Decisions, Decisions

In recent years, the research and development landscape in the pharmaceutical industry has radically changed. The search for the next big blockbuster has been replaced by the search for medicines targeted toward specific patient subpopulations or toward diseases with high unmet medical need to make up the gaping hole left by blockbuster patent expiries.

To supplement their portfolios, big pharmaceutical companies are increasingly looking toward partnerships, not only to lessen the costs of developing a compound from scratch but also to take advantage of the wealth of innovation and cutting-edge science found in academia, start-ups, and small biotech companies.

According to Datamonitor's MedTRACK Deals & Alliances 2010 report, 80% of R&D co-development deals made by the top 10 pharmaceutical companies during 2009 were with biotech and smaller pharmaceutical companies. Interestingly, the report also revealed that throughout 2009, Pharma stepped up its deal-making activity most noticeably for candidates in Phase II and Phase III, a trend that is expected to continue as companies look to access products which will grow sales in the near term.

As an example of this trend, last year AstraZeneca announced that it was redirecting up to $1 billion a year toward in-licensing. The move was seen as solid by analysts at Morgan Stanley who suggested that "the reinvestment of internal research savings into in-licensing will yield three times the likely return."

On the other hand, while big pharma is increasingly looking for partnerships or, in effect, new compounds, the choices open to the small, start-up biotech companies are also shifting when it comes to commercializing their products.

Traditionally, the options open to start-ups were to license the asset to a larger pharmaceutical company or to build their own commercial infrastructure. The drawback of out-licensing is that the value of the asset shifts primarily to the partner while the downside of building a commercial infrastructure can be prohibitively expensive and risky, especially if the company only has one asset to commercialize. Therefore, from a biotechnology company perspective making the right decision is extremely significant requiring robust decision criteria to properly assess the optimal route.

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Lacking Commercial Know-How

It should not be a surprise that many start-up biotech companies are built by scientists and entrepreneurs whose primary focus is to assess the clinical value of their product. They may be confident they have a great product based on scientific principles, but they may be less confident about their ability to successfully commercialize it.

It is likely, given all the hard work and commitment the entrepreneurs have invested into their asset(s), they want to do what is best for their molecules. Naturally, keeping hold of all the intellectual property (IP) rights attached to their compounds would be at the heart of such a decision, and if they have access to the required finance, this route may certainly be an attractive option.

However, even if the team feels they have both the finance and commercial know-how to market the product, the challenge, responsibility, and investment required to build a commercial infrastructure may still serve as a deterrent to go it alone.

In addition, the market landscape has changed significantly over the past few years, resulting in both new decision makers and criteria; it has become clear that regulatory success can no longer be correlated with commercial viability. Consequently, if there has been limited market-led thinking injected into the design of the development program, the chances of achieving commercial success in the current environment is low.

It is not hard to see, therefore, why so many start-ups find it attractive to turn to big pharma companies when it comes to moving the product on. Some aspects of the terms pharma companies offer to the start-up companies can be appealing: launch experience, KOL relationships, and a commercial infrastructure, not to mention potential up-front payments, milestone payments, and a royalty stream going forward. Moreover, as the competition for such licensing agreements increases, the deals offered by the bigger partner may become more attractive for the smaller company.

However, there are inherent disadvantages to out-licensing a product to a big pharmaceu-

tical company, the most significant of which are the loss of control of the product and having little-to-no input into how the product is developed and managed going forward. As the experienced partner, the pharmaceutical company normally dictates the direction of the product commercialization and focusing on its own interest. There is also the risk that should the product not live up to expectations or the priorities of the pharmaceutical company shift, the pharmaceutical company might reduce resource levels or even return the rights to the product. Finally, there is no knowing what the future holds for pharmaceutical companies. For example, if it is subject to a merger or acquisition, there is no guarantee that the start-up company's asset will be viewed as a priority in the new company.

While pharmaceutical companies can offer the benefit of sheer economies of scale, this is often only required for bigger, primary care-focused products. Yet these days, start-up/biotech companies are developing specialist products that are marketed to a smaller audience and so they need a customized commercialization program developed for their product.

A Third Way

Given these difficulties, an alternative and often attractive option is to partner with a comprehensive commercial solutions organization. Like big pharma companies, these organizations are able provide a full range of supporting services throughout the product life cycle, from offering clinical, regulatory, health economics, and medical communications support while the product is still in development, to providing a flexible, fully formed commercial team to providing a complete virtual company comprised of all the necessary resources to fully commercialize the brand.

The advantage of this approach is that the biotech company can retain strategic control, while accessing the launch experience and infrastructure of a global pharmaceutical services organization. The scope of the solution can be completely tailored to the individual company's needs. Ultimately, this model allows the start-up company to keep the value of its asset firmly within the company, while commercializing the brand with a trusted partner.

More importantly, it also allows the start-up company the flexibility to tailor the service it receives exactly to its needs at any time during the partnership. The company can upscale or downscale depending on the success of the product and pilot in geographies where the outcome is uncertain. Using this model helps to de-risk the infrastructure exposure of the small company.

The advantage of working with a commercial outsourcing partner, is that its brand solutions teams, for example, work very closely with clients to define the key factors and activities required for a successful launch and commercialization.

In addition, the outsourcing infrastructure model is designed to complement rather than replace the partner's organization. The scope of this partnership can range from creating a complete virtual organization on behalf of the partner, to the provision of all field-based resources, medical communication, branding, and multiple iterations in between, as well as spanning multiple geographies enabling a global reach.

Furthermore, the resources provided by a trusted commercialization partner can operate under the start-up company name, which ensures a corporate presence for that company. In addition, when the time is right, the partner company has the option to incorporate the infrastructure into its own organization. This allows companies to launch a new product with a world-class and highly experienced infrastructure .

Of course, partnering with non-pharma company third-party organizations can raise issues for the start-up company, the most obvious of which is the cost. By licensing the product to a pharmaceutical company, in most cases they avoid having to shoulder initial costs of commercialisation. Working with an outsourcing partner, the start-up would have to find the financing to pay for services provided — as they would if they chose to go it alone. However, many third-party commercialization partners are increasingly recognizing this challenge and are developing solutions whereby they may be able to offset some of the cost and/or share the risk.

Ultimately, each company with an exciting product in development will face different challenges and have different needs. Some science-based companies may prefer the thrill of developing compounds and would rather leave the commercialization work to someone else. Others may want to be involved in the commercialization of the product they have spent many years developing.

Whichever route these innovative companies take, the most important thing is that the approach of using licensing and partnerships to develop and to commercialize new medicines will see the industry continue to help save or improve the lives of patients. PV

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