SCRIP MAGAZINE
September 2004
Pharmaceutical Issues in Perspective

Risky business

What will make European biotech sustainable? Last month, Claude Allary and Catherine Pichereau examined factors preventing the industry's consolidation. This concluding article by Alain J Gilbert and Mark Larkin discusses how it can prosper nonetheless

Most private biotechs today are ill-equipped to survive independently in today's risk-averse world. With venture capital so scarce, partnerships with big pharma and consolidation are two routes that seem likely to play an increasingly important part in their development. Investors and management will therefore need to be more creative in finding paths to sustainability. Could biotechs form part of a supply chain model to pharma, for example, as is seen in other industries? Such a model may require detailed analysis, but the rewards of sustainability and profitability seem ample justification.

Biotechnology will always be inherently risky – 63% of compounds in development fail in Phase I, 31% in Phase II and 63% in Phase III, according to CMR International. Furthermore, the rigour of the regulatory process stretches out developmental time to more than ten years. The challenge, therefore, is for biotechs to find a business model which secures the long-term development of their pipelines.

A survey of some 200 private biotech companies, which make up the portfolios of the top 35 European life sciences venture capital funds, suggests that this is now fairly urgent. The companies were analysed for their ability to achieve sustainability and rated on Bionest Sustainability Index criteria, which includes management experience, years of cash, maturity of the product portfolio, business model, and external collaborations signed.

And it revealed that only a small minority of the survey had the elements thought necessary to reach maturity. Moreover, the companies that scored highly may still fail to grow because, as said, the biotech world is inherently risky.

Investment trends

The relative merits of business models are complicated by cycles of investment trends. For instance, interest in the human genome spawned a growth in valuations of genomics companies such as Millennium and Human Genome Sciences in the late 1990s, followed by a similar fashion for functional genomics, proteomics and functional proteomics companies later on. In early 2002, however, the hype dried up, valuations largely declined and emphasis started shifting towards top-line revenues and bottom-line earnings. This was the same path that followed the discovery of monoclonal antibodies in 1975. Companies rushed to develop them but hopes were crushed and valuations dropped when high allergic responses associated with chimeric or mouse-derived antibodies were seen in humans.

In these turbulent times, can biotechs afford to go it alone?
Photograph from Corbis

There is a real danger that companies become chameleons, fitting in with the latest trends in order to raise finance. If this process is limited to creative marketing with the goal of pleasing venture capitalists and raising valuations, then it may be relatively harmless. If, however, companies go as far as to modify their business models, then they could lose sight of their core skill-set, which could be disastrous for their long-term viability.

If investment trends induce biotechs to dilute the focus on their core skills, they will probably also lose sight of fundamentals such as competitive advantage and profitability. When the investment climate is not favourable for a company's business model, rather than moving away from its area of expertise, a better strategy would be to join forces with another company in the hope that two areas of activity – both based on core skills – would be more appealing to investors. In the long run, there is far more chance of making money by creating than by following trends.

Platforms *vs* products

Some business models are less sustainable than others. The so-called platform companies that emerged in the 1990s to provide technologies that can improve the overall drug development process are an example of an idea not working out as well as planned. While a new technology can initially produce a handful of lucrative contracts with big pharma companies, in the long run, it can quickly become obsolete, significantly cheaper elsewhere and/or customers find ways to perform it in-house.

Classic business models based on drug development remain the most attractive – and sustainable – in biotech. Few venture capitalists will raise new funds for biotech investments, and those established ones are likely to be with companies with products already in the clinic and with collaborations signed.

Moreover, because of the increased popularity of product companies with candidates in Phase I or II, there will be even fewer biotechs who can count on (re)financing as a component of their plans to reach profitability. These short-term (and thus critical) difficulties in raising finance for early-stage companies are potentially harmful for private European biotechs.

One response to this lack of venture capital before Phase I or Phase II is to seek alternative sources of finance – including public funds, business angels and pharma companies, many of whom have internal venture funds. Biotechs will therefore need to learn how to align themselves to the interests of these multiple shareholder groups that are now entering the financing business.

Time for action

The difficult climate will inevitably result in casualties. In the absence of additional financial resources, the choices are relatively simple: a partnership with an established pharma player, a combination with another biotech…or bankruptcy.

The Bionest study mentioned earlier underlined not only the immaturity of the private European biotech sector but also confirmed the need for imminent action, either through partnerships with big pharma or M&A. But most merger activity in Europe is still usually motivated by pragmatism (cost reductions from infrastructure and facilities can represent up to 30-45% of the cost base of small firms). Strategic consolidation, with its financial and strategic logic based on business synergies, is what the sector needs – and lacks.

So is there a different business model which could provide a mechanism for small biotechs to reach maturity? As so often happens when an impasse is reached, inspiration can come from the reapplication of ideas developed in other sectors.

Perhaps the problems of the immature biotech industry could be viewed as a supply chain problem: a dwindling number of dominant pharma players being serviced by a huge number of biotech suppliers. Whether the biotechs supply services (R&D technologies) or products (therapeutic molecules), the current model requires some of the biggest companies in the world to sign a multiplicity of often tiny (a US$1million deal is a drop in Pfizer's ocean) contracts.

In the automotive industry, however, the big players such as General Motors and BMW have long since stopped dealing with individual suppliers for the myriad components that make up a car. In the 1980s, suppliers began to consolidate to increase their negotiation power with the majors. Even if the latter had to go through tougher negotiations, the overall process was far simpler as they had to deal with only a handful of suppliers.

A preliminary consideration of the logic of this type of supply chain in the life sciences industry seems appealing. Beyond synergies, small biotechs organising themselves into larger entities based around, say, a therapeutic area or a particular metabolic pathway could present a number of advantages. Typically, in a merger or an acquisition, only the best products and technologies are kept, thereby enhancing both companies' product offerings. With a better and broader portfolio, the conglomerate's internal risk is lower than each company on its own and attempts to raise funds or reach deals with big pharma are thus likely to be based on better financial terms. A single supplier offering a number of products spanning, say, GPCRs or RNAis, would have greater power in negotiating contracts.

This more client-focused approach has been lacking in biotech's dealings with big pharma. The smaller company often strug-

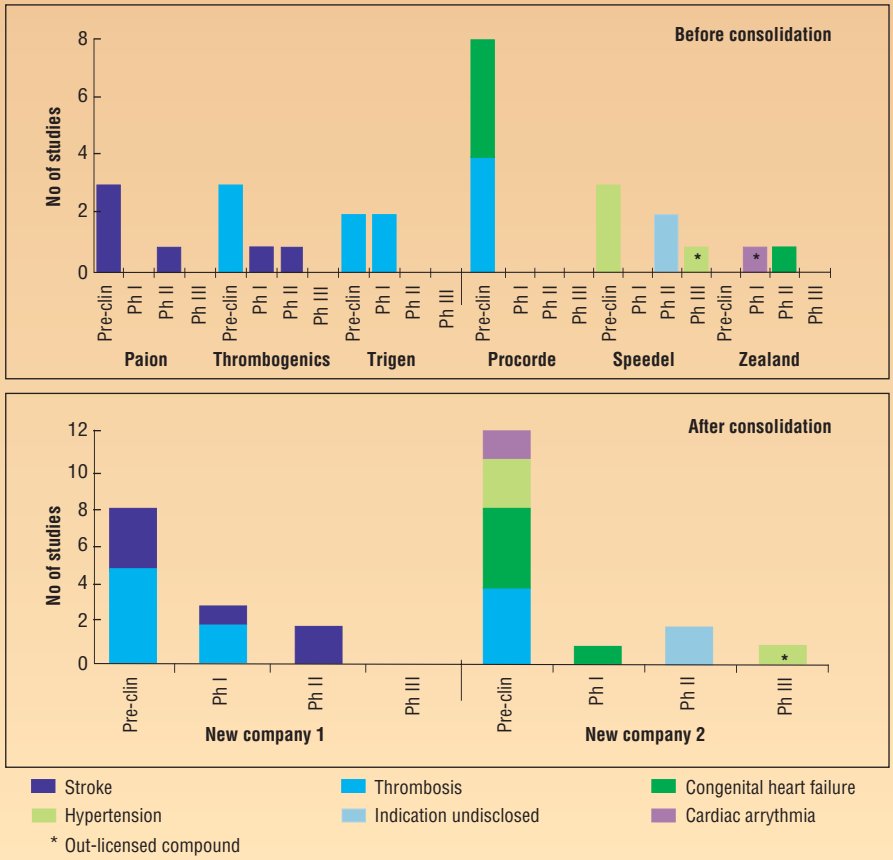
Cardiovascular cluster consolidation

A preliminary analysis of the private European cardiovascular biotechs was carried out, encompassing six development stage companies (Paion, ProCorde, Speedel, Thrombogenics, Trigen, and Zealand Pharma), and four earlier stage companies (ConoGenetix, Kourion, Larnax, and Vasopharm Biotech). The analysis focused on their pipelines and shareholders. An additional consideration of the likely deal synergies and impact on cash burn would be a vital component of further analyses, but impossible here without more complete information.

Two European cardiovascular suppliers are suggested: Newco1, based on the clustering of Paion, Thrombogenics, and Trigen, in thrombosis and stroke; and Newco2, based on the combination of Procorde, Speedel and Zealand, principally in hypertension and congestive heart failure (CHF), as shown below.

Precise percentage shareholdings in the Newcos would not be known until full valuations and negotiations are complete. However, likely principal VC shareholders in the Newcos would be key drivers of instigating the consolidation process. For instance, the inputs of 3i (holders of Paion and Procorde) and Healthcap (holders of Trigen) would be crucial.

This example only serves as a preliminary illustration of the type of entity that could result from clustering. The increased scale of the new entity is attractive, and would be a powerful calling card as a supplier to big pharma clients, and for other niche suppliers who could subsequently join, not to mention a likely facilitation of fundraising. Furthermore, this example is just one of many possibilities – a wider analysis of other therapeutic areas could produce more attractive examples. Clusters with more than one parent company concentrated in a particular region (eg the South East of the UK or the Berlin area in Germany) would simplify the merger transactions. Or, clusters based on parent companies with more shareholders in common could produce Newco ownerships with one or more dominant shareholders that could instigate and drive the clustering process. Although the necessary transaction would be complex, it need not be prohibitively so, and merits at least a closer consideration from VCs and biotech management teams.



gles to sign contracts because it cannot demonstrate the competitive advantage of its product offering: a new technology may increase accuracy in the R&D process, for instance, but if accuracy is not a limiting factor, who cares? However, if the offering aligns products and services, is conveniently bundled and filtered for value-added potential, this would make customers' lives easier. One-stop-shopping has revolutionised many other sectors, so why not life sciences?

This model would result in some business development activities becoming externalised from big pharma. Suppliers would become the clearing houses for the cutting-edge technologies and therapeutic candidates that had previously been offered directly to big pharma. These suppliers would be closer to the technology and therefore better able to evaluate it, letting pharma concentrate on its core skills within drug development. Also, having established relationships with pharma customers, the new enlarged supplier would be in a good position to negotiate terms with companies wishing to join its consortium.

If this model is so compelling, why is it not yet reality? The most important factor may be a lack of creativity among managers and fund managers when considering strategic alternatives. Admittedly, the consolidation model is not straightforward, with the initial consolidation deals likely to be long and complicated. But there is scant alternative. Europe has yet to find a model to transform its strong fundamental research into a commensurate biotech industry. Until it does, good ideas will continue to die or get exported to the US.

Promoting consolidation

As at the birth of the biotech industry 20 years ago, perhaps visionaries are needed to overcome the scepticism of the mainstream and merit a more open-minded consideration of consolidation alternatives. One possible combination is outlined in Figure 1.

To begin the consolidation process, stakeholders (managers, venture capitalists or public bodies) should assess the strengths and weakness of their holdings in the light of sustainability criteria. How could these holdings play a part in a one-stop-shop offering to pharma clients? For venture capitalists or public bodies this may mean undertaking a thorough assessment of their portfolios from which the possible fit into a supply cluster could be envisioned.

Public organisations could also play a greater role in supporting development. In Europe, governments (for example, in the UK and Germany) have played a prominent role in creating their biotech industries. But direct grants are now switching to indirect assistance, such as tax breaks. Other indirect measures such as advice could help companies mature and also improve the return of the initial public investment at both country and EU level.

In short, stakeholders at all levels have a role to play in the maturing of the biotech industry. And all biotechs – whether they are in pre-failure, performing well, or negotiating contracts – should always be thinking of ways to tailor product offerings to customers needs. This is second nature in other industries, so why not in biotech? SM

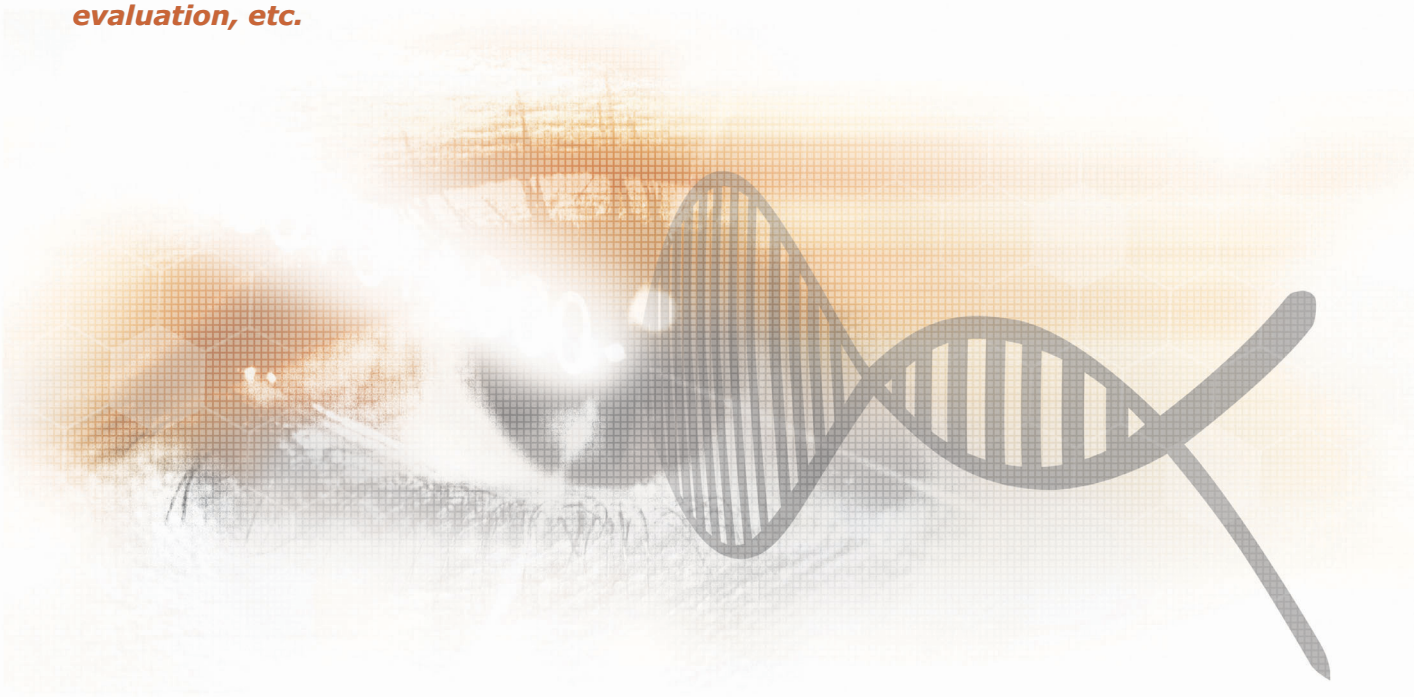
•Alain J Gilbert is managing partner and Mark Larkin a senior consultant at Bionest Partners, a professional services and M&A boutique providing strategic and operational consulting services to innovative healthcare companies. Both authors are based in France.

BIONEST
PARTNERS

Strategy design for Entry in Europe

STRATEGIC
Best entry in Europe strategy for North American companies

OPERATIONAL
Organizational design, HQ location, financial and tax, supply chain, partner evaluation, etc.



Support for Early Access Programs

STRATEGIC
"Early Access" program design for innovative orphan drugs

OPERATIONAL
Bionest Partners' dedicated "Early Access" division will take responsibility - on behalf of clients - for full implementation and management of European EAPs

For more details visit our website or send an e-mail to xavier@bionest.com
Bionest Partners - 13 rue Vivienne - 75002 Paris
Tel : +33 1 58 05 14 00 / Fax : +33 1 58 05 14 09