Corporate development in biotechnology in 2005

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Abstract

In 1998 the author produced two papers which argued that consolidation was a necessary activity for biotechnology companies to consider more. Three years later a further consideration of the subject was published. Corporate developments in biotechnology in the first decade of the 21st century are now considered.

BACKGROUND

Apart from the author's three previous papers,[1–3] the subject of consolidation in the biotechnology industry is a frequent visitor to the pages of the *Journal of Commercial Biotechnology* (and other commentaries). As recently as September 2003, the *Journal of Commercial Biotechnology* carried three papers which made substantial mention of the subject. Bialojan and Schüler[4] reviewed the scene in Germany and commented that 'arguably, the majority of the current German companies lack the critical mass for sustainability; consolidation will inevitably also result in insolvencies and liquidations'. Stoiber[5] discussed challenges to the European biotechnology industry and proposed several points regarding the strengthening of current companies; although he did not strongly promote mergers and acquisitions (M&A), it is clear that he perceived this as one way of achieving a better long-term position. He focused somewhat more on the idea of developing robust and financially viable strategies; this is valid because M&A is not of itself a strategy but merely one of the mechanisms for delivering good business strategies. Finally, Pavlou[6] analysed many recent M&A deals involving biotechnology companies, categorising them into seven groups (two inter-sector and five intra-sector). He considered a total of 82 deals with a 'face value' of over US$45bn in the period 1999–2003 and concluded 'Consolidation activity is expected to move the emerging companies closer to full integration and potentially to sustainable profitability'.

Given this interest in the subject, the present paper attempts to view consolidation in a historical context, with a forward look to the coming years, and as (at least to some extent) an alternative to partnering. But, much more importantly, the paper regards it as a means for biotechnology companies to be in a strong enough position to enter into partnering negotiations in the spirit of combining their core competencies with those of a partner with complementary skills (especially in sales) rather than as financially starved supplicants.

INTRODUCTION

In 1982, Genentech obtained approval to introduce a human insulin product made in bacteria that had been modified to express the relevant gene; this was the first therapeutic product from the modern biotechnology sector. The company's financial resources were limited and so it turned to Lilly for help with manufacture and marketing. When Amgen, one of the other early biotechnology companies and today the largest and most profitable, obtained clearance to launch erythropoietin in 1989 it offered marketing rights to Ortho, part of Johnson & Johnson, though it retained the right to make sales under its own name. Partnering between biotechnology companies and large pharmaceutical

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companies started right at the beginning of the modern biotechnology era.

In the 1980s, it was assumed that biotechnology products would, in due course, earn their discoverers enough to build international companies with their own salesforces. It was a surprise (and disappointment) to many that this turned out to be difficult, indeed verging on the impossible. Amgen has, arguably, reached FIPCO (Fully Integrated Pharmaceutical Company) status but even Genentech does not market internationally, relying on its majority (but arm's-length) equity owner, Roche, for most of its non-US commercialisation effort. Genzyme of course continues to pursue its own independent path – but it always had a different approach from its peers.

There are six indisputable facts in three key areas (research, sales and finance):

Many factors favour partnering

- as a class, biotechnology companies have strengths in research and early stage development;
- large pharmaceutical companies seem to be experiencing a research famine despite spending ever more on R&D;[7]
- biotechnology companies find it difficult to build marketing and sales operations except when their products fit into niche areas which can be reached with comparatively few people (as Amgen did);
- large pharmaceutical companies have massive sales operations with up to 10,000 people on the road in the USA and 30,000 or more worldwide;
- most biotechnology companies are short of money, often chronically, with a survival index (cash and short-term instruments divided by burn rate) of, typically, less than two years;
- at present (though one suspects this might change) large pharmaceutical companies generate large positive cash flows.

Thus it is not surprising that, in 2004, biotechnology companies and pharmaceutical companies seek mutually beneficial partnerships. In exchange for commercial rights to new products from product-based biotechnology companies, the pharmaceutical companies provide some or all of late-stage clinical trials management, regulatory affairs, manufacturing and sales/marketing. It seems that there are natural potential marriages, building on each other's core capabilities, between the large pharmaceutical companies and the smaller biotechnology ones.

Product deals are structured to give an agreed division of the rewards arising from successful commercial exploitation. This is represented by a royalty on sales, eventually, and several payments (up-front fee, milestones, etc) that allow for the delay, which might be several years, before royalties start to flow. A further element in some deals is an equity investment by the larger company, usually of the order of 10–20 per cent; however, this may act as a constraint when the company is addressing later strategic developments. Of course, technology platform companies without their own products relate to their customers, including pharmaceutical companies, through what amount to service contracts, which are generally simpler in concept and content.

Merck has been reported[8] to receive (willingly) several thousand propositions each year, to investigate around 350 in considerable detail and to do some 50 deals in a year. There is no reason to expect any seriously different numbers in the other large companies, though there are of course informal rankings of companies as to which are good (or poor) to deal with; Merck appears to be well regarded. However, there are several issues that make the apparently obvious strategy of partnering more problematic than it might seem. These issues surface in a number of ways and the smaller company is almost always in the weaker position.

FINDING A PARTNER

But partnering is difficult – before, during and after the 'marriage'

The numbers conspire to make finding a partner increasingly difficult. In 1998, there were some 2,500 biotechnology companies and only about 25 large potential partners with near global reach. On the, admittedly heroic, assumption that each biotechnology company had one product to bring forward, it is clear that each pharmaceutical company was being faced with an average of some 100 opportunities *if* each biotechnology company approached only one large company; though, in practice, each will approach several. It is important to note here that few, if any, large pharmaceutical companies operate a clinical pipeline with as many as 50 APIs (active pharmaceutical ingredients).

By 2004, the ratios had worsened with a total of around 4,500 biotechnology companies facing up to only around 15 large pharmaceutical companies. Thus, the ratio had declined from about 100:1 to something nearer to 300:1. The precise number does not matter; but that it is unquestionably large and getting worse are fundamental points.

GETTING THE DEAL

If Merck is inundated with proposals, the same will be true of the other larger companies. A key issue for a biotechnology company is isolating the right partner and coming to an agreement, which both parties perceive as fair, in a realistic time scale. This presupposes that the deal is one which is selected by the large company as worthy of serious effort on its behalf. Merck's 50 deals a year out of several thousand propositions suggests that the large companies are often spoilt for choice. Consequently, the process is normally protracted and there are many disappointments – after all only one in seven of those examined in detail actually come to fruition; a much larger number are dropped before that. All positive deals take a number of months to be sealed and the typical time elapse is somewhere in the range of 9–15 months. The time lag makes heavy demands on the smaller company's resources since it must continue to work (expensively) on the new product throughout the intervening months rather than simply marking time.

MAINTAINING THE DEAL

Keeping the deal alive and in progress is also a demanding requirement. Several factors militate against this. The most obvious one is of course any suggestion that the product is not performing to expectations. Other factors also need to be considered:

- Is the internal champion (the key individual in the big company who is committed to the deal and the product) still in place or has he/she been reassigned to another task or job? Without the continued commitment of the champion there must be doubt that the project will continue with the same emphasis (after all there will be intense competition between in-licensed products for resources).

- Does the internal research effort of the large company produce something that is either directly competitive or just more interesting as a home for the big company's resources? In one sense, there is a near certainty that the internal research effort will throw up options which, as internal products, may offer better margins; strategically, the big company will only accept products/projects that meet its planned needs and these are precisely the fields in which its own effort is already focused. Morally, of course, the big company should/would put its own discovery effort in the same field on ice, pending positive progress with the external product. But it seems likely that the risk of a conflict will always exist. This risk is presumably greater with some partners than others and the informal 'news/gossip' about the trustworthiness of the various big companies will be an important consideration.

- What happens if the larger company loses interest because of budgetary or other constraints? Hopefully, the deal will have been structured to facilitate a straightforward and relatively painless divorce should this happen. This issue surfaced at an unusually late stage (after commercialisation) in the deal between the Australian company Biota and its partner GSK for the anti-flu treatment Relenza. Biota has indicated, by court action,[9] that it believes that GSK did not place enough marketing effort behind the product. Revealingly, the slide in Relenza's marketing position appears to have occurred early in the year 2000 and to have coincided with the merger that formed GSK (such mega-mergers are usually justified by the cost-savings which can be achieved and may generate conflicts as two product portfolios are integrated).

- What is the outcome if the deal progresses but the terms of the deal are re-opened for negotiation at a late stage? The argument between Abbott and Cambridge Antibody Technology (CAT) over the appropriate royalty rate for Humira (launched in late 2002) is a case in point; an announcement in December 2004 suggested that CAT will prevail and receive larger royalties but Abbott has indicated its intention to appeal (this is not an obviously friendly relationship!). It is relevant to note that CAT's original deal was with the BASF subsidiary, Knoll, which Abbott later acquired.

- What is the impact of corporate reorganisation on the part of the big company? Celltech's deal with Pharmacia for CDP-870 (widely perceived at the time to be an excellent deal for Celltech) came under pressure when Pfizer purchased Pharmacia. The fall-out from Sanofi-Synthelabo's takeover of Aventis is still awaited (as at 31st December, 2004), but an article[10] in *Nature Biotechnology* said 'The deal is expected to negatively affect many of the 200 or so R&D collaborations that Aventis has set up with biotech companies, given that Sanofi prefers in-house R&D to such collaborations'.

Clearly, the concept of a prenuptial agreement is of use beyond the high-earning personal fields of property magnates, actresses, footballers and models. But, equally clearly, the relative powers of the large company and the small company come into play. In this context, one has to remember that the product/project may be one of many for the big company and one of just one for the small company. Perhaps Biota's agreement with GSK did not contain adequate constraints on the bigger company to perform (but the relevant clauses may have been the maximum achievable when the deal was signed) and now the former's future must be in some doubt. Celltech, which was financially strong at the time, reacquired CDP-870 and was able to make a new licensing deal, with UCB Pharma.

This new deal was set up in a way that meant that the acquisition of Celltech by UCB was the logical conclusion; the takeover was announced quite quickly after the licence was concluded. Partnership deals that include an equity element may well lead inexorably to the acquisition of the biotechnology company by the pharmaceutical company; the UCB purchase of Celltech just happened unusually quickly after the initial partnership deal.

CHANGING BUSINESS MODELS UP TO 2000

Biotechnology business models have changed over time

As noted earlier, the hope that biotechnology companies could seriously develop to FIPCO status was soon shown to be illusory and the defining moment was Genentech's move into the orbit of Roche. Initially, Roche took a majority stake and then carried out a complex reorganisation in which it took complete

ownership and then floated a modicum of shares leaving it with a controlling stake.

Since the FIPCO model came to be seen as impractical, at least by organic development, the partnering model became essentially the only game in town for most biotechnology companies. In the mid/late 1990s, partnering negotiations were almost always carried out under two constraints:

- pharmaceutical companies still largely believed that they could manage to create a worthwhile number of new products from their own research efforts;
- prior to the funding spree of late 1999 and early 2000 almost all biotechnology companies were cash poor and often needed a deal quite urgently.

Thus, at that time, partnering negotiations usually took place against a background of small company weakness – indeed, *partnering from weakness* is an apt description of the norm.

THE IMPACT OF 2000

Why did the best ever funding year create long term problems?

The (somewhat premature) hype about the Human Genome Project combined with the high-technology boom in the financial markets led to a huge change in the relative security of biotechnology companies. Capital inputs to biotechnology reached unheard of levels with the US sector raising in excess of US$32bn in that year,[11] there were lower amounts raised in Europe but still more in that year than in any other before or since. The result was a major division in the biotechnology arena:

- The more mature biotechnology companies with good records to date were able to raise unprecedented sums of money. Companies such as Genentech, Millennium and HGS became financially secure with cash reserves far in excess of their then current burn rates. Many others raised sufficient to be at low risk of financial failure.
- Many new companies were started in 2000 with venture money, often with implicit backing from government-provided soft money (the rapid expansion in the number of German companies is merely a case in point). The subsequent 2001/2002 fall in the markets and the closure of minor markets such as the Neuer Markt meant that by 2003 the class of 2000 was compelled to live on a shoe-string. There was also a knock-on effect on the rate of new company formation with venture capitalists compelled to husband their limited resources (many could not raise new funds for at least two years) to support those companies in which they had already invested and could not take to IPO.

While many companies were fragile, there was a significant number of companies (perhaps 300–500) that were able to face the next two/four years with equanimity. These companies had the funds to progress their projects further and to get well into Phase II (or even further) before contemplating deals. By waiting later they were able to negotiate with big companies (when they decided they needed to and wanted to) from a position of some strength; to put it simply, they could afford to wait and to drive hard bargains. One of the classic examples was Celltech's ability to conduct an auction for the rights to CDP-870; an auction that was won by Pharmacia.

At the same time, it became apparent that the research efforts of the big pharmaceutical companies were failing to create as many new products as they needed to maintain their product portfolios in the face of a rash of patent expiries (accompanied by enhanced capability among generic companies) in the period 2003–2007. Jan Leschley drew attention to this in a seminal article[12] in which he calculated that the large companies needed (quickly) to acquire or

develop products with a combined annual sales potential of US$110bn. He added: 'one of the reasons why big pharma companies are consolidating is to create a bigger R&D capability by merging their already enormous R&D engines, and make savings that can be ploughed back into R&D budgets'.

Evidence of the strain faced by these companies was crystallised in the 'urge-to-merge' led by the formation of GSK and the Warner-Lambert takeover by Pfizer. And, in 2004, even the Japanese companies started to get in on the act with Fujisawa and Yamanouchi announcing their intention to merge. But, not without surprise to many observers, the merger rush was itself destructive of capability. In an interview,[13] Bob Ruffolo (President of R&D at Wyeth) said: 'Mergers are hard and they are disruptive. Typically, you see a three year paralysis in R&D following a merger, especially if it's not done right, and I suspect they disrupt other parts of the company as well'.

Pharmaceutical companies need biotechnology more than ever

By 2004, it was clear how few new products the large companies were actually producing. It was only in 2001 that BMS indicated a willingness to expand the proportion of in-licensed products in its late stage pipeline to some 25 per cent. By 2004, 40 per cent or more as in-licensed products was not unusual in most large pharmaceutical companies.

Thus, between 2000 and 2003 there was a sea-change in the partnering world. The larger biotechnology companies were financially secure (for the foreseeable future) and the needs of the big pharmaceutical companies for new products had increased substantially. It became possible to talk about a new model – *partnering from strength*. Hard bargains could be driven, but only by those companies that had accumulated strength; arguably the weak ones were in an even worse position in 2003 than was the case in 1998.

An example, possibly not widely known, is Alizyme, which has, with a total employee base of fewer than 20, managed to get four products into the clinic with three in, or entering, Phase III in 2004/5. Announcing its annual results in September 2004 and referring to the anti-obesity product ATL-962, the CEO, Richard Palmer, said 'We have had a lot of meetings with interested parties. The main issue for us is to find a partner with commitment; our cash position enables us to continue to negotiate from a position of strength'.[14]

IS A NEW MODEL POSSIBLE?

Several factors imply that new business models are now possible, if not essential. The reduced number of really large pharmaceutical companies (largely the result of the urge-to-merge) means that they are no longer the only potential recipients of the creativity of biotechnology companies. Moreover, if the large pharmaceutical companies continue to experience a decline in R&D output, in the face of serious shortfalls in contribution as patents on blockbusters expire in the period 2004–07, their high fixed cost bases will be exposed. Most big pharmaceutical companies have low variable costs (10–20 per cent of revenue) and high fixed costs (in the order of 60 per cent of current revenues) mostly in R&D and marketing/sales. The possibility exists that they will have to re-trench or that the amount of spare cash that they have available to in-licence products will decline sharply. Current pricing issues in the USA (where they obtain around 40 per cent of their sales and nearer 70 per cent of their profits) may also exacerbate this issue. Medicare reforms may expand volumes but will probably depress prices, while parallel importation (opposed by the big pharmaceutical companies, the FDA and the Federal Government) will continue as individual states (Wisconsin, Illinois, New Hampshire, Maine and Maryland seem to be in the lead) promote it.

Thus, perforce, biotechnology companies are now driven to seek partners in hitherto neglected groups. Mid-size pharmaceutical companies (Novo, Leo, Merck KG and UCB

Pharma are examples) are also product hungry and the largest biotechnology companies (Amgen, Genentech, Chiron, Genzyme and Serono, for example) increasingly have the resources and capabilities (including financial) to be potential partners for smaller companies. Thus, one can anticipate smaller biotechnology companies having the opportunity to pitch their wares at a wider group of candidate partners than was the case in 1999. Because the larger Japanese companies are rarely players outside their home territory, they are not usually partner candidates except in Japan.

The larger biotechnology companies are cementing their positions through deals to take products and in many cases to acquire smaller companies 'lock, stock and barrel'. Amgen has widened its product portfolio by the acquisitions of Immunex and Tularik (the latter at a cost of US$1.3bn – paid in stock); Genzyme is buying Ilex; Biogen and IDEC merged in 2003; Chiron purchased Powderject. In doing so, they are creating enhanced capabilities beyond their pre-existing R&D operations to add manufacturing and marketing/distribution capabilities, though not yet with the sheer size of the sales operations of the major pharmaceutical groups. Thus, the previously fragmented biotechnology value chain (from research to marketing) is being consolidated to create FIPCOs (or something close to them) by these companies. Few though seem likely to develop enough to become full global players; but much stronger regional players focused on the USA or Europe seem very plausible.

Biotechnology companies need to be stronger

In this environment what should be the response of the smaller companies? It is clear that:

- the number of smaller companies is not sustainable at its present level; this is especially so in Europe where there are 1,861 companies[15] but only 96 (just 5 per cent) that are mature enough to have quoted stock (compare the US numbers of 314 quoted companies out of a total of 1,473 – 21 per cent);
- many of the smaller companies are financially fragile and may not be able to sustain themselves until they can bring their products to Phase II, the traditional threshold for partnering;
- investors continue to be impatient for results and so fund raising, though now possible again after the 2001–03 drought, is not an option available to all companies (indeed, there are signs that smaller companies are finding it difficult to raise finance without favourable clinical results – but this is not universally true and in some cases it may be a consequence of their projects just not being very attractive to any investor that has been approached);
- the expanded pool of potential partners among speciality pharmaceutical companies and larger biotechnology companies may well not be able to absorb the wealth of new products from biotechnology companies; it has been reported that more than 370 biotechnology products are now in clinical development;[16]
- there needs to be space, in terms of financial and management resources, to build new entities based on the continued outpouring of outstanding basic research in the leading Universities (Stanford, UCSF, UCSD, MIT, Cambridge and Imperial College, for example) and independent research organisations such as the Whitehead Institute (Boston, MA), the Scripps Institute (La Jolla) and the Laboratory of Molecular Biology (Cambridge, UK).

There are signs that building strength by amalgamation is an attractive option for many companies. Celltech merged with Chiroscience and bought Medeva,

Biotechnology companies can be independent of big pharmaceutical companies

did the Pharmacia deal, purchased OGS and then allied itself with UCB Pharma in the space of about four years. Ribotargets merged with British Biotechnology (a problem child since it fell from grace in the late 1990s) and then joined with Vernalis – the combined company with a strong Ribotargets element in its management now trades under the name Vernalis. It is a demonstrably stronger company with a substantial product portfolio, in-depth management and a sound financial position. It is noteworthy, incidentally, that Peter Fellner, former CEO of Celltech, was an engineer of the corporate development of both Celltech and Vernalis.

It should also be noted that the M&A activities mentioned in the previous paragraph involved companies that did not have significant equity elements in their previous partnering deals. Genentech's majority owner is Roche and clearly no other party could buy Genentech without Roche's approval. Roche also owns (somewhat indirectly) about 8 per cent of Antisoma and has an effective call option on the company's development pipeline. In late 2004, AstraZeneca announced its intention to take a 20 per cent share in Cambridge Antibody Technology (CAT) with the parties jointly working on selected projects. Is it possible that these stakes will constrain the freedom of Antisoma and CAT to negotiate partnership deals with, or trade sales to, other parties?

SUMMARY AND CONCLUSIONS

Can others duplicate the consolidation approach via M&A? The answer to this question may well be that they are doomed if they do not. This analysis points to the need for managements to face up to the changing situation. The original desire for FIPCO status by organic growth was unrealistic. Partnering from weakness gave way to partnering from strength. The next step is the creation of viable product businesses for the long term. Some of them may well achieve something approaching FIPCO status in due course.

We should note at this point that technology platforms are now recognised for what they are – qualitatively and quantitatively different creatures from product-based companies. It is widely understood that platform companies can earn fair returns, and do so relatively quickly, but not the margins of product companies. While BioFocus is a successful supplier of combinatorial chemistry and high-throughput screening services, and on its 2003 financial results, close to profitable, it is valued by the financial markets as a service supplier. Revealingly, it is valued at half the level of a small product company such as Phytopharm which has only 15 per cent of its revenue, a larger R&D budget, is loss-making and has 80 per cent fewer employees. The number of sustainable platform companies is probably small. This means that many platform companies are trying hard to convert themselves into product companies but lack the internally generated financial resources to do so and, often, have no access to external sources.

Many product companies subsist on the hope that one product (or a narrow focus) will enable them to develop. But one-trick ponies are often fragile and cannot sustain a setback (Cantab Pharmaceuticals and OGS are merely two examples, of many, of companies that have been subject to distress sale where the price was close to the target's cash in bank).

The 2000 IPO class of genomic companies (19 in number) has suffered a severe down-rating with an average decline in market capitalisation between 2000 and 2003 of nearly 60 per cent, only 1 of the 19 experienced an increase in value. But, genomics is now an unfashionable term and three leading genomics companies (dating back well before 2000) have transformed themselves, some quicker than others. In 1995, Millennium, HGS and Incyte all offered a skill base. Now these three companies have moved significantly, capitalising on the funding opportunities

of 2000, towards a product orientation. Indeed, Millennium started this process long ago and purchased additional skills that it needed, including the medicinal chemistry skills that it acquired with Cambridge Drug Discovery and the product and marketing base of COR Therapeutics.

What to do and what will happen if some biotechnology companies lead the creation of strong companies?

A plausible scenario for corporate development in 2005 is for a far-sighted management group (with the benefit of accommodating investors) to merge three or more product companies and perhaps to add a platform company (with particularly relevant competencies) and/or another supplier of relevant services. The result will be a much smaller number of companies with three key characteristics:

- a technology profile allowing the pursuit of a pipeline of four to eight quality product candidates and the skill base to optimise their development;
- a dedicated management team given time to find good deals negotiated from a position of strength;
- a financial base capable of carrying a cash burn for more like five years than the rather more typical small company survival index of one to two years.

There will be several beneficial results from this type of development:

- stronger, more sustainable companies;
- attractive long-term investment opportunities, which will attract back the larger investors[17] that gave up on biotechnology in 2001/02;
- visibility in mid-cap markets (eg FT 250);
- an opportunity to recycle entrepreneurial managers able to get more new companies started to enhance the outpouring of academic research.

As a final note, there needs to be a word of caution. This was memorably described by a Wall Street banker in the pithy phrase 'merging two dogs usually creates a bigger dog'. In other words, the proposed development of larger companies through M&A will only succeed if there is a conscious decision by venture investors to focus their attention on product sets which are outstanding enough to create viable pipeline portfolios. The unfortunate conclusion is that they also need to recognise that some existing companies are not going to succeed. This may be particularly true of platform companies without the resources to transmute themselves into viable product companies; quite possibly their limited resources may be better deployed elsewhere.

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