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Testing times for the pharmaceuticals industry

As big drug companies face problems in getting new products approved, they are becoming ever more reliant on biotechnology, says Geoff Dyer

If Bristol-Myers Squibb's falling-out with ImClone, a small biotechnology company in which it has invested $2bn, was just a one-off event arising from a hasty deal, the pharmaceuticals industry would have little to worry about. But the dispute cannot be dismissed so easily. Coming at a time when the industry's best-selling brands face increasing competition from cheap generics, and its pipeline of new products is thin, the stand-off exposes a further vulnerability - the big drug companies' deepening dependency on the biotech sector.

Most large pharmaceuticals companies have built a web of alliances over the past decade with innovative biotechnology groups. But the industry is still learning how to handle the risks this collaboration brings. Biotech companies are sometimes accused of cutting corners to get drugs approved and to overstate their effectiveness.

For Bristol-Myers Squibb, one of the largest US pharmaceutical companies, it has been a hard lesson. Its shares, which were already cheap compared with its rivals', have fallen 11 per cent since the US Food and Drug Administration rejected ImClone's cancer drug in December.

"Everyone is going to be much more careful about doing more due diligence on these deals - about the science, the intellectual property and about the trials," says Bill Kridel, managing director of Ferghana Partners, an investment bank specialising in biotech.

Bristol-Myers' investment in ImClone is one of the biggest deals to date between an established drugs company and a biotech partner. To get access to Erbitux, ImClone's promising colon cancer drug, Bristol-Myers paid $1bn for a 20 per cent stake in the company and promised further payments of up to $1bn.

The relationship has turned sour since the FDA's announcement that the drug could not be approved because of faulty data in the clinical trial. Bristol-Myers has demanded more control over the development of the drug and that ImClone's two most senior executives temporarily stand down. ImClone has refused. ImClone is also being threatened with legal action by some shareholders who claim that it gave misleading information about its previous dealings with the FDA. Congressional hearings could also be held.

Bristol-Myers, meanwhile, is trying to fend off the impression that it was so desperate to get its hands on a seemingly promising new drug that it spent $2bn without doing its homework. "The lesson from ImClone is that companies need more rigorous procedures for doing deals," says Peter Barrett of Atlas Venture, a venture capital firm.

The dispute between Bristol-Myers and ImClone comes at a testing time for the pharmaceuticals sector. The drug companies are desperate for new products: over the next 5 years, drugs with annual sales of $40bn are expected to go off patent. At the same time, political pressure in the US and Europe is limiting the companies' ability to increase prices.

The biggest problem they face, however, is the poor results of their own research and development, which is costing more but producing less. Eight of the top 15 pharmaceutical companies did not win approval for a single new drug last year. According to Jean-Pierre Garnier, chief executive of Glaxo-SmithKline, in 1980 the top 20 drugs companies spent $2bn on R&D and 34 new drugs were approved. Last year, the top 20 spent $26bn, yet only 28 drugs got the nod. "You cannot deny that it costs us more money than ever to find new products," he says.

Bristol-Myers Squibb is suffering more than most. Earnings are expected to fall by up to 7 per cent this year as three of its biggest drugs begin to face competition from low-cost generics.

The biotech industry, by contrast, has been getting stronger. The decoding of the human genome has allowed record fundraising over the last two years. There are now about 500 biotechnology companies researching new products, and they have about 1,300 compounds in development.

Hence the increased collaboration. Some pharmaceutical groups spend up to 30 per cent of their research budgets on alliances with external partners. Pfizer, the world's largest drugs company, has more than 1,000 projects with academia or biotechs. Bristol-Myers Squibbs' deal with ImClone was the most aggressive by a big pharmaceuticals company last year, but it followed large transactions between Pharmacia and Celltech, a UK biotech group, and between Eli Lilly and the much smaller Isis Pharmaceuticals.

Now, however, the ImClone dispute is forcing the industry to think hard about how it handles these deals. The most important issue is the due diligence. "The key to any deal is to look at all the correspondence between the FDA and the biotech firm," says Rolf Stahel, chief executive of Shire Pharmaceuticals, the UK-based speciality pharmaceuticals firm.

Clear division of responsibilities is another requirement. While pharmaceuticals groups want to tap the inventiveness of the biotech companies' scientists, they usually feel they are better at doing late-stage development and at dealing with regulators.

Pharmaceutical companies also need organised management structures to assess and run alliances. "Getting out of a deal if it does not work is just as important as getting in," says Mr Kridel.

More fundamentally, the R&D crisis has sparked a debate about what a pharmaceuticals company should focus on. Several have decentralised their research groups into semi-independent divisions to try to recreate some of the atmosphere of the biotech world. One senior GlaxoSmithKline executive has even gone so far as to say it could spin off parts of its drug discovery business if the results did not improve.

"Size is not something that works in R&D," says Jacques Theurillat, finance director at Serono, Europe's largest biotech group. "Big pharma companies will more and more become marketing and distribution engines, leaving the research and science to biotech companies."

That said, the big drug companies are not abandoning in-house research yet. Many have invested heavily in genetic technology, which they hope will make it quicker to find new drugs. "Because we fail in most of what we do, it does not take a massive turnaround to significantly boost R&D productivity," says Mr Garnier, noting that only one in 10 drugs that enters clinical trials makes it to market.

But for the pharmaceuticals industry, the lessons of the ImClone experience are clear. In the past, investors paid most attention to the big drug companies' science and their ability to produce new drugs. In future, they will look just as closely at how well they manage deals.