## COVER STORY



# LIFE SCIENCES: GASPING FOR BREATH



REPRINTED FROM:

JULY 2010 ISSUE

© 2010 Financier Worldwide Limited. Permission to use this reprint has been granted by the publisher.

www.financierworldwide.com





The environment for life sciences companies can differ widely between smaller players and industry giants. For newer businesses, 2010 has been a difficult year, but certainly better than

### COVER STORY

the two that preceded it. Their limited levels of capital mean they now have to rethink strategies and become more prudent when deploying capital. Partnerships with larger pharmaceuticals, mergers with other smaller businesses and monetisation of existing royalty and revenue streams have all become more common. However, companies not perceived to hold any assets of value are struggling, and experts warn that some of them will not be able to ride out the current credit crisis. "For smaller players, the supply chain, creation of product demand and working with the right people are all key issues," highlights Sunil Thacker, "a ugpkqt"rey {er" "In times "of recession, the smaller players often find it very difficult to reduce costs and develop new business models. The costs associated with research and development in Europe, America and Asia are very high and smaller players face a stiff challenge in meeting these costs, further affecting research & development budget allocation." In addition, throughout the crisis, valuations of smaller companies often come in relatively low, therefore extending the gap between industry majors and smaller rivals.

#### Big player advantage

At the other end of the spectrum, larger players have the cash reserves and revenue generation to better navigate a crisis. Yet they still face challenges. The economic uncertainty has forced a drop in share prices, while US healthcare reforms and pending patent expirations raise doubts over future strategies. "Nevertheless, big pharma has the size and flexibility to adapt to the changing environment by restructuring their internal organisation, altering their commercial or development focus, or expanding into emerging markets, either through direct sales activity or through acquisition of companies in South America, Asia and the Middle East," says John Leone, a partner at Paul Capital Healthcare. Indeed, large companies are better prepared to adapt to changes in regional economies and the global economy as a whole. "As for smaller companies, those with valuable assets are being creative with leveraging them for partnerships, mergers or alternative financing strategies. Overall, the smaller companies are under greater constraints than the larger companies," he adds.

For businesses of all sizes, the expiration of patents and the growth of generics will have a significant impact on how companies adapt their strategies towards future growth. Experts point out the best way for big pharma to mitigate any losses from patent expiration is to introduce new compounds. However, given the sheer volume of patents due to expire and the huge sales they generate, it will be difficult to replace such vast lost income over the short term. Market leaders must therefore study alternatives to enhancing R&D productivity and replace any lost sales. M&A is now being used as a means of increasing partnerships between large pharma and biotechs looking to expand access to promising compounds. However, while R&D-based acquisitions may help to boost future sales in the mid to long term, more immediate strategies are required to replace lost sales. Recent activity does

suggest pharmaceutical companies have recognised the need to produce generic products and gain a foothold in what is a growing segment.

But the assumption that generics will automatically thrive should not be taken for granted. In a Deloitte report discussing the future of the life sciences industry, Eyal Desheh, CFO of Israeli-based Teva, the world's largest producer of generics, stated that the generics market is very different to other segments of life sciences. Deloitte also added that the scale of the generics market in a country is not only determined by cost pressures, but also by the regulatory environment. For instance, the 1984 Hatch-Waxman Act, which liberalised the regulation of generics in the US, is the chief reason behind the country's \$59bn market today. Unless a branded product is explicitly indicated, pharmacists in the US are required to change branded prescriptions to generics. However, in other developed markets, presumptions still exist that generic goods are inferior. For example, in Japan a pharmacist may only dispense a generic product if it is specified in the prescription, in complete contrast to the US.

What is more, the generics industry is now highly competitive. Although just a decade ago the industry comprised of many different producers, a series of consolidations resulted in just a handful of major players remaining. However, the example of Teva is proof that it is possible to generate a successful business based on the generics model. Net sales of \$3.9bn in the final quarter of 2009 were 25 percent higher than last year. However, Mr Desheh was quick to point out that his company invests more of its revenue back into development of new generics than any other. Indeed, Teva's portfolio of over 400 drugs makes it bigger than its nearest three competitors combined.

#### **Emerging markets**

Another imperative is to push into developing markets, not just India and China, either through expansion of existing infrastructure or by acquiring local companies. Mr Thacker points out that life sciences have gained momentum throughout the Middle East region. "The industry is primarily composed of companies specialising in fields of biotechnology, biomedical devices, testing laboratories, pharmaceutical and research. World class infrastructure, zero tax economy, repatriation of profits and relaxed regulations have all attracted several life science companies to the Middle East," he notes. "To illustrate this, the introduction of Dubai Biotechnology and Research Park and of the Qatar Science and Technology Park (QSTP) has attracted several biotech and pharmaceutical companies to set up their base." But Mr Thacker points out that there remains a need for institutional guidance and IT infrastructure to support the industry, refining its efficiency and building on innovation.

Prior to the recession, the desire of life sciences companies to expand meant that emerging markets, in particular the BRIC nations (Brazil, Russia, India and China), became a focus. In collaboration with Deloitte, the Economist Intelligence Unit (EIU) conducted an online survey of 281 senior executives at the back end of last year. Of those questioned, 32 percent said they still planned to accelerate geographical diversification after the global recession. Just over a third of respondents also felt that one of the main affects of the recession on the shape and size of life sciences industries over the next five years would be the rise of emerging markets. One of the industry leaders, Sanofi-Aventis, in a presentation to investors about its long-term commitment to emerging locations, emphasised that the BRICs together with Mexico and Turkey were home to 45 percent of the world's population but accounted for just 10 percent of global prescription drug sales. As these economies become wealthier and the cases of chronic disease increase, so too will the demand for lucrative products to treat them. Sanofi, which already has a large portfolio of prescription brands, over the counter products, generics and vaccines, is positioning itself to take full advantage of these fast growing markets by increasing its focus in such regions.

However, as there are no guarantees of success for newcomers in the generics market, emerging countries are also far from a sure bet. Analysts believe that, first and foremost, companies will have to persuade individuals in such markets to spend more and save less. Speaking to Deloitte, industry participants have suggested that healthcare spend is rising in countries like China, where an 8-9 percent increase in GDP is expected. However, in China's case this has been brought on by state investment and not by individuals' spending. Furthermore, although medical products might be considered to have generic users across the world, taking products designed by Western markets and trying to sell them in regions such as the Far East can result in a mismatch of producers and consumers. Markets are different and local R&D is essential. Pharmaceuticals such as Sanofi-Aventis have looked to distance themselves from global branding in developing markets, operating instead under a series of sub-brands with local meaning. The company is also pushing through local R&D activities so that products are specifically aimed at the local population.

#### Research and development

Pharmaceuticals should not lose sight of the importance of R&D, which remains a critical component for generating new product lines and can refill their portfolio of patented products. Although R&D has in the past been outsourced, among big pharma in particular, the process is considered too important to the success of a company for it not to have direct control. Rather than abandoning their in-house projects, companies are using the current downturn as an opportunity to enhance their internal processes, making acquisitions and acquiring partners under more favourable terms, which may not have been possible just a few years ago. However, as Mr Leone explains, the decision for smaller companies is more difficult. "They often need to decide if they are going to be technology platform companies or one-product companies, and invest their capital resources accordingly," he suggests. "Platform companies will need to make small investments across a number of programs that validate the platform. Product companies will need to narrow their pipelines and put their resources into moving one program forward as quickly as possible, striving to reach a point where partnering, buyout or commercialisation becomes feasible." As it stands, venture-backed companies appear to be

For businesses of all sizes, the expiration of patents and the growth of generics will have a significant impact on how companies adapt their strategies towards future growth.

more focused on narrow product development efforts. Nonetheless, it is worth remembering that businesses that have alternative forms of capital, such as royalty or revenue streams, can be monetised. Such businesses will therefore be better positioned to make strategic investments in R&D.

A further downshift in R&D would not bode well for the life sciences industry. Experts warn that R&D remains the chief driver behind innovation and competition. It is up to companies themselves to do more with less, as far as research expenditure is concerned. Outsourcing, although not ideal, should still be a consideration. Contract research organisations are setting up their base in tax free economies such as the UAE and Qatar, for example. Larger companies, with cash on their books, remain the best placed to make acquisitions. The financial crisis has made this even easier, as smaller companies are less able to withstand the advances of larger rivals, given their need for critical capital to continue or even simply survive. Although larger players will now have a bigger pool of prospective targets, they will also face more competition from other larger companies encouraged onto the acquisition trail by the distressed valuations on offer. Offsetting this is the growing number of smaller companies joining forces, allowing them to reach a balance of cash and products and ultimately survive. For example, a company which has cash but no near-term product opportunities may partner with a business that has portfolio potential but insufficient capital to exploit that potential.

Smaller companies are gradually beginning to see light at the end of the tunnel, abandoning the idea of being bought or licensing products. Some of these companies are seeking alternative forms of capital that will allow them to delay partnerships until they attain a more valuable stage of development, or retain products for commercialisation. Nonetheless, stronger players must still show a level of diligence when ascertaining whether synergies can indeed be achieved through acquiring a rival. Where there is evidence of post-merger profits, companies can go on to strike deals with rivals, establishing an immediate presence in other countries and acquiring rights to patents and other intellectual property belonging to the target.

Sunil Thacker is a senior lawyer at STA Law Firm, Dubai. He the healthcare industry in business transactions, including joint ventures, private placements, structuring of physician organizations, financing, acquisitions, mergers, advising on licensing, health-care regulations, and structuring aspects throughout the GCC. He can be reached by telephone on +971-4-3689727 or by email on corporate@stalawfirm.com