Editorial: Creating a competitive European life science sector

Can Europe nurture a sustainable life science sector that can compete with the US sector? Moreover, can this be achieved by 2010, and how? This is the goal of the European Commission that is vexing politicians, entrepreneurs and investors throughout Europe. The European life science small and medium-sized enterprise (SME) sector has witnessed unprecedented growth in the last ten years but, according to Ernst and Young, this growth stalled/reversed in 2002 with total revenues down 2 per cent to €12.9bn and the total number of employees down 6 per cent to 82,100.[1] Aside from the tough macroeconomic environment, growth is hampered by inadequate funding at all stages of SME development, fragmented and inefficient financial markets, and lack of commonality on pricing, patents and clinical trials. It is fair to say, however, that progress is finally being made on the Community patent, albeit after about 12 years of debate.

Seeking to foster innovation and sustain economic growth, the EC published a strategy paper and action plan in 2002, 'Life sciences – A strategy for Europe', setting out the ambitious goal of creating the 'most dynamic economy by 2010'.[2] This was endorsed by the European Parliament. One of several expert groups established to help implement the EC's plan, the Biotech and Finance Forum Working Group (BFF WG), was set up under the auspices of the EC, EuropaBio (EB), the European Investment Bank (EIB) and European Investment Fund (EIF), to examine potential funding gaps and recommend appropriate measures to address them. For the unquoted sector alone, a funding gap of about €1bn over 2003 was forecast. For the quoted sector, the situation is more depressed, with virtually no institutional investment and a high proportion of stocks trading below their cash per share valuations – a clear sign that the market believes many ongoing projects are potentially without merit and value is actually being destroyed.

Since the 2000/2001 bubble, quoted companies have received very little funding; according to Private Equity Online,[3] 90 per cent of all life science funding came from venture capitalists (VCs). At the end of 2001, Ernst & Young reported that there were 59 per cent more life science companies in Europe than the USA,[4] although AltAssets Inc.[5] calculated that there is one specialist life science VC firm for every eight life science companies in the USA, compared with only one for every 19 companies in Europe.

The BFF WG looked at how more public funds might be provided to help keep the sector on its growth trajectory, fearing a vicious spiral in terms of bankruptcies and investor confidence that would prolong the cyclical downturn and result in destruction of much value built over the last decade or so. Concerned about the structural problems in the sector in Europe (too many non-viable businesses), together with the bottleneck due to the absence of an initial public offering (IPO) market, illiquidity in the public markets and the lack of specialist venture and institutional investors in Europe, the BFF WG recommended that significant public funding needs to be channelled through independent, specialist life science investors. This funding would need to take the form of traditional mid- to late-stage venture capital and crossover funds, where the capital requirements of funding clinical trial development through to proof of concept are

placing an intolerable burden on financial investors and resulting in stagnating unfunded projects. Of course, not all projects deserve to be financed, but in this environment many viable projects are suffering too from lack of resources.

The European Commission provides support principally through its Framework Programme and by attempting to ensure coherent policy initiatives throughout member states – perhaps its greatest challenge. Waldemar Kütt, Etienne Magnien and Mark Cantley outline the priorities of the 6th Framework programme (FWP6) in 'The role of the European Commission in fostering innovation in the life sciences and biotechnology' in this issue. It is of note that 15 per cent or €337.5m of the total €2.25bn dedicated to life sciences, genomics and biotechnology for health is set aside for SMEs up until 2006. Also included in this programme are fellowships for SMEs to help stem/reverse the brain drain and facilitate technology transfer to industry in Europe. For the first time, this public funding is also available for early stage clinical development. Providing this can be accessed in an efficient manner and help companies maintain a 'first in class' or similar competitive position, this could provide helpful additional support. The European Commission has responded to past criticism from the industry concerning the difficulty in accessing funds by making application conditions more flexible and more meaningful funds available. While commendable, it remains to be seen how successful this programme will be for Europe's SMEs, when compared for example to the National Institutes of Health's (NIH) SBIR (Small Business Innovation Research) programme. It is also doubtful that it will have much impact on Europe's competitive position, given the relative size of the NIH grants (about US$24bn in total for 2002 alone) and the relatively greater SBIR programmes (eg the National Cancer Institute alone awarded US$79.4m to domestic SMEs in 2002).[6] Europe could well benefit from a similar institution and grant system for innovation.

In addition to EC funding, there have been a number of member state initiatives, most notably the BioRegio competition which kick-started the German sector in 1996. This and similar initiatives helped to promote a more entrepreneurial culture in Europe, but they are partly responsible for the sector crisis we see today. The barriers to entry for SMEs have been virtually non-existent and the sector in Europe has simply grown too fast, while growth of the support industry, including financial backers, has failed to keep pace. But this is too simplistic: there are many other structural challenges faced by the industry, not least the high proportion of one technology, one product, non-viable businesses as alluded to earlier.

In this climate of scarce funds, some countries have been hit harder than others, with the average venture capital financing in Germany only €4m compared with a European average of €9m. By contrast, French and Scandinavian SMEs have been relatively well backed. Germany has been hit especially hard at a time when its sector is at its most vulnerable. Julia Schüler and Siegfried Bialojan, in their paper 'Commercial biotechnology in Germany: An overview' highlight this. BioRegio funding and other state initiatives have successfully jump-started the sector, but Dr Schüler and her colleague question how state aid matches the industry needs. It is striking that the sector in Germany has yet to bring a drug to the market, although roughly 10–12 years are necessary and the German sector has had a relatively recent start. Moreover, the fact that the German pharmaceutical industry is having a particularly unproductive and difficult period, resulting in few potential spin-out or in-licensing opportunities, is not helpful to the rapid maturation of the domestic SME sector. There is much internal competition between different regions, and Dr Schüler and her co-author stress the need for a unified approach to help push forward supportive political decisions, especially on the tax front. France Biotech has been particularly successful in this regard, although formal ratification of fiscal measures approved by the French Parliament by the Competition Commission is eagerly awaited at the time of writing.

Beneficial fiscal measures are all very well and good, but companies need to deliver products and offer investors attractive investment opportunities. Gone are the days when investors could trust in backing the bell-wether companies in their domestic markets to provide a superior return. This is a truly global industry and good role models remain scarce in Europe. The pending acquisition of one of the few successful profitable companies, Powderject plc, by Chiron Inc. may be great news for Powderject shareholders, but it typifies many of the concerns of the European Commission.

William Brooks, in his paper 'What will it take to get institutional investors interested in life sciences again?', also points to the lack of specialist investors, and draws attention to the relative lack of interest among US investors in the European sector, with a few exceptions. This is perhaps not surprising, given the abundance of more mature, more liquid investment opportunities in the USA. Dr Brooks's paper discusses the main factors influencing investors, namely the macroeconomic environment, product development success, financial stability and critical mass. Dr Brooks believes that loss of over 50 per cent of the companies in Europe today would be very damaging. Yet it is difficult to envisage less of a shake-out in Europe over the next five years or so, given that 20 years after the birth of the US sector, critical mass and stability was achieved with about 1,200 companies. Until quoted prices rise, there will continue to be a bottleneck of late stage private, poorly financed and therefore stagnating companies unable to provide their investors with liquidity to recycle cash into younger companies. The only means to make these companies more attractive to a wider institutional shareholder base is to build critical mass and more mature pipelines – both will take time and money.

Will consolidation in Europe's sector help revive its lacklustre stock market performance and help create more robust companies? Wolfgang Stoiber's paper 'Consolidation challenges in Europe's life science sector – Making it happen' examines the success factors in mergers and acquisitions (M&A). He points out that the FIBCO model, still a desirable goal of most companies, is difficult to achieve today, given the earlier exploitation of low hanging fruit, mostly by US companies. Dr Stoiber gives some examples of successful FIBCOs and mergers, again mostly US. Celltech plc is perhaps the best example of a European company that has successfully grown its business by acquisition. Most value is created in the final stages of drug development and Europe has a relatively immature drug pipeline. Most concerning for Europe's politicians, entrepreneurs and investors is Dr Stoiber's assertion that the relatively late start and focus on technology make it difficult to imagine companies in Europe carving out a major piece of the value chain created by companies that exploit their technology by bringing products to market. Even companies that do achieve the FIBCO model in Europe do not appear to command the same relative valuations as their US counterparts owing to perceived lower quality of earnings.

So can Europe close the competitiveness gap with the USA by 2010 as the EC desires? Dr Stoiber's paper helps provide the short answer – no. As outlined, this is partly due to the late start in Europe, lengthy product life cycles, lack of low-hanging fruit which has been already exploited by US companies, together with the commoditisation of many of the technologies being developed in Europe's biotechnology companies.

It is perhaps unrealistic to envisage that meaningful public funds will be provided in the short term to help the sector mature and grow. While the European Commission and member states ponder measures to improve the business environment for life science SMEs, the competitiveness gap will continue to widen. Efforts to date to level the playing field, while laudable, can best be described as 'tinkering at the edges'. While many tax incentives are not immediately helpful to loss-making companies, the ability to trade tax losses carried forward with potential pharmaceutical and other profitable corporate partners could be meaningful in enabling life science SMEs to convert

significant tax losses to cash. This is one of the many measures being considered by the UK's Bioscience Innovation and Growth Team. Greater incentives for financial investors willing to fund innovation is also absolutely necessary.

Europe needs to get its act together fast if the competitiveness gap with the USA is to close. Post-enlargement, with 25 accession countries, Europe will represent a theoretically larger drug market in terms of value than the USA, particularly if ethical pharmaceutical pricing pressure is brought to bear by President Bush. Ironically, this might inadvertently help level the playing field more than any measures that Europe could take, and help stem the flow of pharmaceutical business from Europe to the USA. Somehow this seems doubtful. Nevertheless, enlargement will present serious additional challenges, including greater competition for public and private funds. In conclusion, short of a miracle, it is difficult to envisage the EC meeting its 2010 goals.

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References

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This issue of *Journal of Commercial Biotechnology* focuses on financing, but also features additional papers that cover other topics, including licensing trends, the impact of pharmacogenetics, how to comply with the Sarbanes-Oxley Act and new models for the biotechnology market. A further paper examining health economics and its role in the growth of the biotech industry can be found in the online version of this issue and will be printed in the next issue of the Journal. To view the online version of the Journal, please go to the HSP website at www.henrystewart.com