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Entry into Europe – companies from overseas face critical issues

BENEFITS AND BARRIERS IN THE BIOTECH SECTOR

What can the European biotech sector offer a non-European? Although few non-Europeans would deny the attraction of the huge end-market, many have been discouraged by financing difficulties, and onerous fiscal and regulatory frameworks. Many of these critical issues have been recognized and have begun to be tackled, in an effort to unshackle the industry and – the constant subtext – to compete more effectively with the US.

Overview

The European biotechnology sector remains immature by comparison with the US, but can still boast a variety of s ub-sectors of interest to non-Europeans. Drug development remains the dominant sub sector – both in terms of development of therapeutic products themselves, as well as in terms of business models based on providing technologies and services to developers. Financing problems have forced some of the latter to try to mould themselves into product companies, with varying results. Beyond this, the sector also includes bio-agricultural and bionutritional sectors that have emerged from Europe's traditional strength in the agrifood sector, as well as the emerging field of nanobiotechnology. Despite commercial immaturity, the European end-market is approximately the same size as that of the US, and increased in 2004 with EU enlargement.

Finance

Germany, France, and the UK are the leading EU biotech countries, due to close ties with traditional agricultural, chemicals and pharmaceuticals sectors, aligned with strong academic research. Furthermore, up to several years ago, important government innovation funding programmes have resulted in a glut of start-ups in countries such as Germany. Development finance, however, is more scarce, leaving many companies facing tough choices to avoid bankruptcy. Few companies have had the foresight and/or experience to embrace consolidation early, and fewer still have achieved IPOs. In the US, the barrier between biotech and pharma is blurring through mature giants such as Amgen, Biogen, and Genentech, but even relatively mature European biotechs find it difficult to break out of the biotech bracket, and are often consequently snapped up by overseas investors long before they could even approach the status of the US biotech champions. Even the UK, the most mature of European biotech sectors, has not escaped this trend with, for instance, Powderject being acquired by Chiron (US), and more recently Celltech by UCB (Belgium).

This lack of maturity is backed up by a forthcoming Bionest report[1] on the state of the European biotech sector in Europe, which includes a survey of 20 key European biotech opinion leaders. Although European academic research was acknowledged to be strong, in the experts' views, transforming this into commercial success remains subject to significant hurdles, including lack of financing and experienced management (although there are some signs that a critical mass of managerial experience is being reached in the most developed areas, such as the UK).

The difficulty experienced by biotechs in reaching maturity is one of the reasons for the current European popularity of spin-offs from established big pharma players. Spin-offs have the advantage of experienced management teams and ready-made R&D programs from Day One, with the parent company often retaining part of the share capital of the company, for added stability. For investors, these factors lower the risk profile, especially relative to 'raw' start-ups. Europe's large pharma industry provides many interesting spin-off opportunities, and the latest pharma mega-merger; of France's Aventis and Sanofi-Synthélabo, is likely to add to this number. A recent example is the Swiss infectious diseases and dermatology company, Basilea, which was spun-out of Roche. Basilea achieved its IPO earlier this year and, although its stock has underperformed, this could be argued to reflect more sector-wide sentiment than company specific shortcomings. The fact remains that Basilea's has been one of the few biotechs to go public this year, and its status as a spin-off contributed in no small part to this success.

Fiscal framework

Many European countries have had a relatively high tax burden, at both the corporate and personal level. In recent years, many countries have recognized that the only way that Europe can compete with cheaper labour in the developing world is to transform into 'knowledge-based economies'. This means encouraging innovation-based sectors, such as biotech, through both direct grants and indirect measures aimed at lightening the tax burden. These latter measures vary by country, but in the UK, France and Germany, for instance, biotechs are eligible for a suite of tax breaks, often following the US model, which have made for a far more attractive fiscal climate. Ireland is the EU country that has been most active, with the adoption of aggressive fiscal measures over recent years in an effort to promote

innovative/high tech sectors. Life sciences as well as IT and telecoms have consequently boomed in Ireland as a result of both overseas investment and indigenous growth.

EU research funding
In addition to these national incentives, some finance is available for biotechnology research at the European level under the EU sixth Framework Programme (FP6). This extensive programme, running from 2003 to 2006, has an overall budget of Euro 17.5bn, of which over Euro 2bn is earmarked for life sciences. Both academic and commercial research is eligible for financing, provided certain criteria are met, including the use of an international team from more than one EU country. The main problems of FP6 are the labyrinthine application procedure and the lengthy delay before funds are transferred, which have proved significant barriers to those applicants with the most meagre resources – who are also those in most need of assistance. Despite these difficulties, FP6 can nonetheless be a significant source of R&D finance for European biotech.

Regulatory process
European biotechnology has long had to grapple with a long and expensive regulatory process, based on different national legislations. Again, the comparison with the US, where the Food and Drug Administration (FDA) is the sole arbiter of regulatory approval, is not favourable. Drug developers must devote significant resources to regulatory approvals in each target market, knowing that approval delays and refusals can be economically catastrophic, particularly for biotechs, who often have little or no financial room for manoeuvre. However, the establishment of an EU-wide regulatory body, the European Agency for the Evaluation of Medicinal Products (EMEA), in 1995 streamlined the process somewhat, although member countries still exert varying degrees of national autonomy.

Intellectual Property
Patents are crucially important for establishing and protecting the intellectual property which is a cornerstone of biotechnology development. Historically, different patents were required for each country, making patent application processes time-consuming and costing between Euro 50,000 and Euro 100,000 (think of the technical translation costs alone) depending on the number of countries selected, compared with around Euro 10,000 for a US patent. Recently, however, an EU-wide patent was agreed, which should soon accelerate and reduce the cost of patent protection.

Bioethics
Bioethics is a subject which is acutely important to the biotechnology sector, and one which is rapidly evolving in Europe. The use of stem-cells for research and the impact of genetically modified foods on health and the environment are two key issues for both the commercial and academic biotechnologies sector in Europe, although the actual impact varies by European Union member country. In passing legislation allowing stem cell research, the UK government for instance, recognized its potential to health and medicine (and perhaps business); this research is prohibited in Ireland and Spain. By contrast the UK has probably the most militant animal rights lobby in the Europe, which has proved problematic for some UK life sciences companies, most notoriously the contract research organisation Huntingdon Life Sciences, based near Cambridge, whose premises, staff, clients and even investors have been the subject of protests, some violent.
In short, each European member state has a combination of bioethics issues which lead to a unique national profile and attractiveness for the biotechnologies sector. Although most governments are keen to provide the best environment for biotechnology, strong public opinion in certain countries can intervene to create markedly different national bioethics frameworks.

Conclusion
The biotech sector in Europe has piggy-backed on existing strengths in academic research and the well-established pharma/agrifood/chemicals industries. The EU has recognized the importance of the biotech sector for its future economic development and, with many potentially limiting issues being tackled, albeit slowly, the European biotech sector should have more chance of leveraging its undoubted existing strengths and maximizing its potential over coming years.
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REFERENCES
1. "Time for Change? – Prospects for the European biotech industry" – Bionest Partners, 2004

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