Biotechnology perspectives in Europe

Although the current practice of corporate biotechnology was pioneered in the US in the late 1970s and early 1980s, the industry is now global. It is widely acknowledged that the US leads the way in terms of almost any method used to measure corporate biotechnology. However, the European biotechnology market is enjoying probably the fastest and most concerted growth in its history, and represents the most significant developing corporate arena outside the US, becoming within sight of those in the US. However, corporate biotechnology is not always conducted in the same way in Europe as in the US. These differences, which include attitudes towards risk, availability and access to different types of venture capital, government support, patent protection issues, stock market exit routes and others, serve to highlight opportunities as well as bottlenecks. Many of these issues were addressed during the large Biotech Europe 99 conference organized by AIC–ECPI Ltd in London, UK, 22–24 February 1999. In attendance were leading participants of European biotechnology as well as a small number of their US counterparts.

State of the industry

By all accounts, 1998 was a bad year for the industry in terms of monies available in the public markets, both for IPOs and also secondary and other offerings. As was discussed at the meeting, $1.1 billion was raised in the public markets in the US in 1998, versus $2.4 billion in 1997. However, it should also be noted that the private venture money raised in the US in 1998 was almost equal to that of 1997, at $3.3 billion and $3.4 billion, respectively. These figures immediately suggest that biotechnology is characterized by a dichotomy of investor approaches: the private market is always accessible for quality companies, even though the public markets might be jittery and mistrustful. In fact, the theme of the industry's image and perception, and the effects that this has on investors and the public, was developed as part of this meeting and will be described later.

One notion that was demonstrated by factual review was that the European biotechnology market is now in a similar range as its US counterparts. There are now approximately 900 biotechnology companies in Europe and around 1500 in the US. In addition, it should be noted that, whereas five years ago, most biotechnology companies in Europe were based in the UK, France and Germany, at present 14 European Union (EU) members report ten or more biotechnology companies. This is very encouraging in terms of regional development, competition and performance, because to survive, these companies must compete on a global basis.

Key management issues

Having set the scene in terms of the framework of the industry, the meeting addressed a number of critical issues concerning the management of biotechnology from a company perspective. Specifically, key issues included the balance between growing or selling a company, intellectual property issues, and the perspectives of the pharmaceutical industry.

A biotechnology company today faces an important development dilemma: how is real growth best achieved – is it through intrinsic measures or is it simply through the acquisition of another company, and is it best to simply sell the company at the appropriate time? One thing is very clear: as one presenter put it, 'being static is not an option'. In fact, despite a great deal of recent activity in terms of consolidations of biotechnology companies, it was argued that from the perspective of the market, biotechnology still presents more of a static profile, because the market wants large biotechnology companies and the industry consists of lots of small ones. Multiple growth models have been, and are being tried, but with variable success. Growth by acquisition, for example, results in a significant realignment of most of the key features of a company, such as its assets, technology platform, product line-up, patent estate, management and technical talent. The reasons behind such a move, therefore, need very careful evaluation, especially in terms of what the company will look like after the acquisition has occurred. The other side of acquisition is from the perspective of the seller. Again, the reasons need very careful evaluation, as the move implies a loss of control of the sold entity, although this is balanced by the renewed growth potential. One thing that was discussed at this meeting was that, despite the biotechnology industry following numerous business models, even greater creativity is required in the way biotechnological business is performed. This is partly driven by investors in biotechnology, who have seen their recent returns on investment in biotechnology lag behind other sectors, such as the Internet.

Patent issues

Patent rights is another important management issue in the biotechnology industry, as they are one of the unique leverage points for the investors as well as for the company to gain strategic relationships with other companies. Of great interest is the new patent directive issued by the EU in 1998 for biotechnology, which clarifies what can be patented. The salient points are that biological material or processes can be

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patented, whereas human bodies, human cloning processes, processes for modifying germ lines, and the industrial or commercial use of human embryos cannot be patented. In addition, propagated material (except human) may be covered, and the patent rights may crossover between plant varieties. The directive has gone a long way towards clarifying and harmonizing the patent situation in Europe although, as in the US, many cases are likely to be heard and argued in the courts for the first time, and the outcome is therefore still unknown.

Pharmaceutical perspectives

Partnerships with large pharmaceutical firms form a central part of the growth and longevity of a biotechnology company. The meeting, therefore, addressed some key perspectives offered from the pharmaceutical side, in particular, the need for the alignment of goals and expectations to prevent the failure of alliances. A lack of alignment between partners can lead to ineffective communication and hence, no mechanism with which to monitor the alliance. These issues are very important for biotechnology companies, and there is a need to manage expectations and develop trust from the outset, whilst being flexible enough to allow for the evolution of these goals and expectations as the project progresses.

Successful European case studies

To conclude discussions about the nature of success in biotechnology, a number of European case studies were presented. Each case represents a different approach to building a successful biotech company in Europe.

Oxford Glycosciences (OGS, Oxford, UK) is a proteomics-based drug discovery and development company whose business model rests on identifying customer needs, developing efficient market access, differentiating products and services, and providing a clear investment scenario. The company identified the crucial requirement as being the pharmaceutical industry's need for validated drug targets, which requires outsourcing of technology and searching for technology integration. OGS has become successful by developing proteomic databases and tools to aid the pharmaceutical company.

Genzyme NV is the European arm of Genzyme, the highly successful US biotechnology company which is among the top ten largest biotechnology companies worldwide, with more than 3500 employees and a market capital of more than $2 billion. Genzyme NV was established to promote Genzyme's business in Europe, and directly represents Genzyme products in more than 14 countries in Europe. Currently, the company is positioning itself to leverage its European sales and marketing infrastructure to promote new therapeutics as well as to strengthen its leading position in therapeutics targeting lysosomal storage diseases, such as Pompe's, Fabry's and Hurler's diseases.

Artemis is a German company started on the basis of a transatlantic alliance with San Francisco-based Exelixis Pharmaceuticals. Artemis performs genetic, genomic and bioinformatic analysis in vertebrate model organisms. The end result is lead validation screens and targets for the pharmaceutical industry, including diagnostics and animal health products. Artemis complements its US partner which is a model system genetic company focusing on the well-known models of *Drosophila melanogaster* (the common fruit fly) and also the nematode *Caenorhabditis elegans*. The two companies were established such that between them, they have a seamless platform of model organisms to screen for new targets and leads, whilst taking advantage of both European and US biotechnology.

FGene is a French company established with yet another business model in mind. The company systematically selects potential lead molecules for commercialization from academic institutions throughout Europe. By utilizing its well-networked Scientific Advisory Board, the company identifies compounds that satisfy unmet medical needs and have proprietary protection, licences them from their host institution and develops them through proof of principle prior to attempting to partner them at an advanced stage to pharmaceutical partners.

Regional European initiatives

Regional initiatives to build and support a robust biotechnology industry were a key point in terms of European biotechnology, highlighting that specific countries took systematic, thoroughly researched efforts to invest in the infrastructure and incentive scenarios for biotechnology.

The details of the approaches vary between countries. For example, Germany's BioRegio concept is built around three biotechnology clusters in Germany and combines matching funds with infrastructure assistance. In the UK, there are several funding sources complemented with competitions and courses aimed at educating scientists with entrepreneurial instincts and desires. Italy has been regarded as more of an importer and distributor of biotechnology products and services than as a primary producer. However, in the past few years, the Italian Government has established legislation and created funds to help stimulate the efforts of academic groups wishing to enter the corporate arena. Denmark's Medicon Valley Academy was formed in 1997 as a partnership of four Danish and two Swedish universities and includes the Copenhagen Business School, which represents a good example of how both technical and business infrastructure contributions can be combined in an initiative of this type. The Academy aims to catalyse academic–corporate interactions and is active in all fields that can help achieve that

goal. BioResearch Ireland (BRI) has been functioning for more than 11 years and is a partnership between five Irish universities and the Enterprise Ireland Government agency. At present, BRI has established a biotechnology seed fund that will begin investing in 1999 and is developing training programmes for researchers and entrepreneurs. Finally, Switzerland has a national Biotechnology Priority Programme (SPP BioTech), which not only funds academic research, but also focuses on technology transfer through the Biotectra technology transfer office, established in 1996. In addition, as in Germany and the UK, there is a national business plan competition.

Analysing market potential

Finally, the meeting addressed the issue of new advances and how they impact on the development of biotechnology as a whole. In particular, the issue of consolidation among biotechnology companies was revisited as an example of how today's reality of business has a significant impact on the potential development of existing, as well as new technologies and companies. As part of this discussion, the issue of competitive intelligence in biotechnology was raised, highlighting the importance of being well-informed to be able to make the right decisions on both the scientific and the business direction of a company. Here, it was advocated that companies cannot afford to passively accumulate information concerning the industry around them. Companies need to be pro-active in retrieving and analysing information, to enable the planning of their strategy in advance of potentially significant events.

Conclusions

The biotechnology industry, in terms of genetic engineering, systematic lead screening, lead optimization, reagents and services, is more than 20 years old now. It has evolved dramatically in terms of technologies, products and business models. Great success stories include specific drugs as well as pure information, such as that provided by the leading genomics companies. In this maelstrom of activities, the US has traditionally taken the lead, with more companies, greater funds, faster approval for new products, and a more efficient public market than Europe. However, in the last two to three years, Europe has experienced a dramatic growth in its own biotechnology industry, spread across many countries. Although still not quite in the same league in terms of performance measures as the US, Europe boasts many success stories of its own, and there are numerous concerted efforts presently underway. Despite the current trying conditions for the biotechnology industry, in terms of public perception and investor attitudes, there is a great deal of enthusiasm and optimism based on the tremendous potential of the industry, its results to date, and its pipeline of new products for the future. These issues and more were addressed at the recent London meeting, as described above, which provided an excellent forum for the exchange of ideas from leading practitioners in the field.

Aris Persidis
Argonex Inc., 2044 India Road
Charlottesville, VA 22901, USA
tel: +1 804 975 4300
fax: +1 804 975 4301
e-mail: apersidis@argonex.com