

Biotechnology commercialization in the world

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Review

Abstract

One of the greatest challenges for researchers is converting scientific discoveries and innovations into successful companies. To succeed, the spin-off phase of biotechnology companies has to be crossed by bioentrepreneurs and venture capitalists, reluctant to invest in early stage biotechnology companies. The paper summarizes biotechnology commercialization in the world, marks significant biotechnology and life sciences clusters on the world map and accents results in biotechnology commercialisation in European Union and United States of America.

Keywords: biotechnology commercialisation, spin-off, bioentrepreneur, early stage development

Introduction

There are many issues to be addressed when commercializing biotechnology research. The obvious lack of pre-seed capital and inadequate financial support from government are not always to blame (Pavlou 2003). In many cases, a lack of commercialization skills in the field of biotechnology and innovative financial tools can be the missing factors to capture the significant value from the biotechnology laboratories (Nagle et al. 2003). Although growth and development of biotechnology spin-offs heavily depend on financial recourses, conducive environment is a necessary condition (Booth 2006, Berry 2002). The paper looks into world's

leading biotechnology clusters and companies to summarize major biotechnology commercialization results in the world (Bains 2009).

Global biotechnology

Commercialized biotechnology concentrates in biotechnology clusters surrounded by universities and life sciences research institutes (Moses and Cape 1999, Friedman 2006). The idea of a cluster is geographic concentrations of interconnected actors, building on strengths and removing barriers to development. It requires actions and co-ordination between government departments, devolved administrations, regional economic development agencies, universities, companies and others (Sainsbury 1999). Effective technology transfer is also necessary with a formal legal infrastructure for university participation and sufficient funds to file patents. The formation of new companies requires a business infrastructure in the community, researchers, technology transfer professionals, entrepreneurial company founders, scientists, managers to staff the companies and knowledgeable investors. It takes a whole community to build a biotechnology cluster. Once built, the cluster can achieve a sustaining life that strengthens itself (Nelsen 2005). The world's biggest clusters are San Francisco and Boston area in USA, Cambridge and Oxford area in Great Britain and lastly Medicon Valley and BioValley in the continental Europe. South Pacific Asian and Australian clusters are lately emerged and fast growing areas (Table 1).

Biotechnology in USA

Biotechnology commercialization began in the USA in late seventieth of 20th century. The San Francisco Bay area is in many ways the cradle of the world's biotechnology industry. The 1973 discovery of a practical technique for recombinant DNA production by Stanford's Stanley Cohen and the University of California San Francisco's Herbert Boyer was the breakthrough that opened up the possibility of using genetic engineering to diagnose and combat disease. In 1980 Genentech, the company that Cohen and Boyer founded to commercialize their discovery launched its initial public offering, triggering huge public and investor interest in the biotechnology industry. The area's largest biotechnology firms are Chiron Corporation and Genentech. Since 1995, the area has attracted more than 3 milliards USD in venture capital investment in biopharmaceutical firms. Investments have been made in 261 new firms and 21 venture capital companies are present in the region (Robbins-Roth 2000). The area has had the most initial public offerings by biotech companies since 1998 and

has attracted more than 1 milliard USD in pharmaceutical-biotech research alliances since 1996. The San Francisco area has 90 publicly traded biotech companies with an aggregate market capitalization of nearly \$82 billion. The industry includes 46 firms with more than 100 employees, and 114 firms are members of the national Biotechnology Industry Association (PriceWaterhouseCoopers 2001). A study in 2002 showed that San Francisco region is the most entrepreneurial region among the nine studied (Cortright and Mayer 2002). The biotechnology industry is highly concentrated in nine areas: Boston, Los Angeles, New York, Philadelphia, Raleigh-Durham, San Diego, San Francisco, Seattle, Washington-Baltimore. These nine areas excel because they possess two key ingredients necessary for biotech growth: strong research and the ability to convert that research into commercial activity. The typical biotechnology centre has about eight times as much research activity as other metropolitan areas, about ten times as many large and newly established biotech firms, and about 30 times more venture capital funding. On average, a top biotechnology centre has about nine times as much biotech research activity and about twenty times as much biotech commercialization activity as any of the 42 metropolitan areas that are not biotech centres.

Table 1. World's biotechnology and life sciences clusters with high Growth Competitiveness Index 2004 – 2005 (World Economic Forum, 2006)

| | | |
|--|---------------------------------------|----------------------|
| North America | United Kingdom / Ireland | Oceania |
| Seattle, USA | Glasgow-Edinburgh, Scotland | Brisbane, Australia |
| San Francisco, USA | Manchester-Liverpool, England | Sydney, Australia |
| Los Angeles, USA | London, England | Melbourne, Australia |
| San Diego, USA | Cambridge-SE England | Dunedin, New Zealand |
| Saskatoon, Canada | Dublin, Republic of Ireland | |
| Minneapolis/St. Paul/Rochester USA | | Asia |
| Austin, USA | Continental Europe | Beijing, China |
| Toronto, Canada | Brussels, Belgium | Shanghai, China |
| Montreal, Canada | Medicon Valley, Denmark/Sweden | Shenzhen, China |
| Boston, USA | Stockholm/Uppsala, Sweden | Hong Kong, China |
| New York/New Jersey, USA | Helsinki, Finland | Tokyo-Kanto, Japan |
| Philadelphia, USA | Paris, France | Kansai, Japan |
| Baltimore/Washington, DC, USA | Biovalley, France/Germany/Switzerland | Hokkaido, Japan |
| Research Triangle NC, USA | BioAlps, France/Switzerland | Taipei, Taiwan |
| | Sophia-Antipolis, France | Hsinchu, Taiwan |
| Central America / South America | BioRhine, Germany | Singapore |
| West Havana, Cuba | BioTech Munich, Germany | Dengkil, Malaysia |
| Belo Horizonte/Rio de Janeiro, Brazil | BioCon Valley, Germany | New Delhi, India |
| Sao Paulo, Brazil | | Hyderabad, India |
| | Mideast | Bangalore, India |
| Africa | Israel | |
| Capetown, | | |
| South Africa | | |

The therapeutics sales of the ten leading biotechnology companies (Amgen, Genentech, Serono, Genzyme, Biogen, Chiron, MedImmune, Gilead, IDEC and Celltech) were forecast to grow from 17,4 milliards USD in 2003 to 32,7 milliards USD in 2008. It is Datamonitor's view that a number of key trends extracted from analysis of the therapeutics revenue performances of the leading biotechnology houses could give an insight into the evolution of the global biotechnology sector. Oncology will be the main therapeutic area with sales of over 9,1 milliards USD, accounting for 28 per cent by 2008.

Recombinant proteins will be the most successful platform with 2008 sales of 19,2 milliards USD followed by antibodies and small molecules with forecast sales of 7,6 milliard USD and 3,9 milliard USD in 2008, respectively (Fig. 1). Datamonitor expects the sector to respond with another wave of mergers and acquisitions activity, targeting newly approved or ready-to-launch products in well-protected market segments from the emerging biotechnology or small-sized private pharmaceutical sectors (Pavlou 2003).

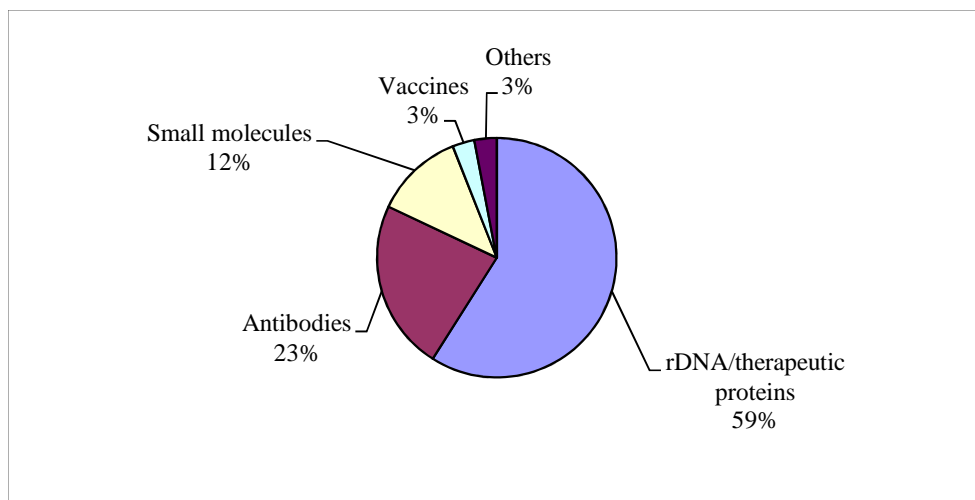


Fig. 1. Therapeutics sales breakdown by technological platform, 2002–2008 (Datamonitor, 2009).

Europe

Biotechnology in Europe plays into the long-term future of a densely populated and interdependent continent that wants to act in a sustainable and local way within a global economic environment (Hodgson 2006). There is a strong need to continue promoting the development of life sciences and biotechnology in the EU, in particular by increasing research

and promoting competitiveness (Commission 2007, Ukropcova and Sturdik 2009). As activities that relate to innovation become increasingly global and draw the private and public sectors into complex networks of partnerships, these activities also tend to concentrate where the system is the most supportive (Dearing 2007). The major event in this field is a European public-private partnership initiative between pharmaceutical industry (European Federation of Pharmaceutical Industry and Associations) and the European Commission (DG Research - health priority) resulting in the European Technology Platform project "Innovative Medicines Initiative". Its architecture is based on the identification of the main bottlenecks to the development of innovative treatments e.g. predictive pharmacology and toxicology, identification and validation of biomarkers, patients' recruitment, risk evaluation, and cooperation with the regulatory authorities (Demotes-Mainard, Canet and Segard 2006).

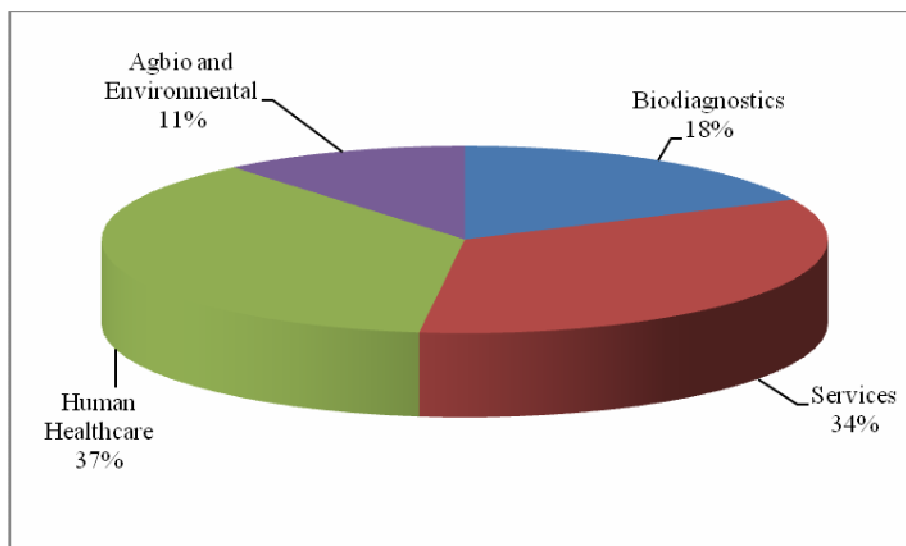


Fig. 2. Breakdown of European companies by sector (EuropaBio, 2006).

In Europe, a third of these companies undertook Healthcare related activities and a further third provided technical, manufacturing or research services (Fig. 2). The remaining small third of European companies were either involved in activities leading to applications in agriculture, food technology, and the environment (Agbio and Environment: 11% of companies), or in the development and manufacturing of biologically-based diagnostics, largely for the diagnosis of human disease (Biodiagnostics: 18% of companies).

The appropriate benchmark for the European industry is the world leader in biotech and Europe's principal competitor, the United States. The European and the US

biotechnology industries both have around 2000 companies (Hodgson 2006). The US sector employs nearly twice as many people, spends around three times as much on research and development. It has twice the number of employees involved in research and development, raises over twice as much venture capital. The US biotech has access to ten times as much as debt finance and it earns twice as much as revenue (Table 2).

Table 2. A snapshot of the EU biotech sector (EuropaBio, 2006).

| In 2006 | Europe | US |
|-----------------------------------|--------|---------|
| Number of companies | 2 330 | 1 991 |
| Number of new companies formed | 131 | 78 |
| Number of employees | 98 500 | 190 500 |
| R & D expenditure (in mld €) | 7,6 | 21 |
| Revenue (in mld €) | 21,5 | 41,5 |
| Venture capital raised (in mld €) | 1,02 | 3,2 |
| Equity raised (in mld €) | 3,65 | 11,3 |
| Debt raised (in mld €) | 0,81 | 7,4 |

Table 3. Top venture funding in Europe in 2006 (Ernst & Young, 2007).

| Name | Country | Round | Amount raised (EURm) |
|----------------------|-------------|--------------|----------------------|
| Movetis | Belgium | First Round | 49 |
| Chroma Therapeutics | UK | Third Round | 44 |
| Cerenis Therapeutics | France | Second Round | 43 |
| Nabriwa Therapeutics | Austria | First Round | 42 |
| Ablynx | Belgium | Fourth Round | 40 |
| Palau Pharma | Spain | First Round | 40 |
| Santaris Pharma | Denmark | Fourth Round | 40 |
| NowImmune | Switzerland | Second Round | 37 |
| Chiasma | Israel | Second Round | 35 |
| ESBA Tech | Switzerland | Third Round | 32 |
| Neuropharma | Spain | Second Round | 32 |
| Genextra | Italy | Second Round | 30 |

The past few years marked a recovery period for the European biotechnology sector. The industry recovered from a financing standpoint in 2005. Looking at 2006, it appears that it is now on the right track of sustained progress. A record year of financing, with EUR 4,7 milliard rose with 45 percent increase demonstrates the robustness and growing strength of

the European biotechnology sector (Table 3). The innovation and commercialization performance are extremely diverse in new member states and accession member states in European Union (Ukropcova and Sturdik 2010). Going under economical transition, the two main features of the restructuring are increased autonomy for scientists and the beginnings of competitive research funding. It is expected, that large concentrations of researchers and technicians in one location will be achieved not only geographically, but through virtual networks as well.

Japan

The Japan Bio Industry Association has been conducting an annual survey on the number of biotechnology companies in Japan since 1998. According to the latest survey, released in January 2004, there are now 387 biotechnology small and medium enterprises in Japan (Mitsumori 2004). Medical and health related businesses account for the largest percentage. The number of venture capital funds is quite limited (Müller and Fujiwara 2002).

Australia

In Australia, because of market structure, the tendency for biotechnology companies to list early in their life cycles has caused problems (Wells, Coady and Inge 2003). In the last few years, Australia has witnessed a growing number of venture capital firms specializing in the bioscience/health industry (from none to nine in two years). These firms understand the nature of investment into the biotechnology sector, including the long-term nature of investments. Venture capital firms also indicate a willingness to 'co-invest' in biotechnology companies – this reflects the high level of risk associated with investing in the sector, but also provides biotechnology companies a valuable opportunity to learn about needs of different investors and rigorous reporting requirements. The lessons for biotechnology companies are not to be lured into listing too early in their product development, but instead to focus on other sources of funding, such as private equity and government grants.

Singapore

Singapore's commitment to the success of biomedical sciences is perhaps best reflected in the Biopolis—a 2-million-square-foot R&D complex that will house key research institutes and private research organizations. Biopolis incorporates facilities specifically tailored for

biomedical companies, including laboratory and office space, incubators to nurture start-up companies, animal handling facilities and laboratory support services (Tang et al. 2003).

China

The Chinese biotech industry is going through a period of fast growth, and with its huge population, China is predicted to be the biggest single-country market in the world. However, the Chinese biotech industry has to tackle the critical issue of higher education and innovation, which should be the driving force into an advanced and responsible development of genetically engineered drugs (Yu and Dai 2006). The government has developed centres such as the Beida Biotechnology Park, Hangzhou Biotechnology Park, Zhongguancun Science Park and Hong Kong Science Park to foster the growth of start-ups with technology spun out of universities as well as scientists returning from overseas to set up their companies using offshore capital. Looking to the future, the 'Action Plan for the Biotechnology Industry' aims for more than 500 active biotech companies by 2011 (Tang et al. 2003, Zhenzhen et al. 2004).

India

The Indian Government has been playing an important role in the development of the biotech sector from the very beginning and there are large numbers of R&D institutions (scientific, medical, industrial and agricultural) that have been set up by the Government during the past 2–3 decades (Konde 2008). The past performance of the industry indicates that it has surpassed the growth rate of many other industries as a consequence of favourable national policies (Kumar et al. 2004). According to the Biotech Consortium India Limited survey, there are in total 176 biotechnology firms present in India out of which 49 per cent are agriculture based companies while 25 per cent companies have interest in the health related medical activities and 26 per cent companies have varied interests including in environmental biotechnology (Chaturvedi 2002).

Conclusion

It is becoming a reality in the world that biotechnology and life sciences are the frontier of a knowledge-based society. The global biopharmaceutical industry with over 70 milliard USD in revenues and 700 publicly listed firms posting double-digit growth in North America, Europe, and Asia-Pacific in 2006, represents an attractive and promising industry of the future

(Ahn and Meeks 2008). Broad scientific advances and commercial successes have captured the attention and aspirations of policy makers, business people, and investors in high-growth sector.

Biotechnology is an industry sector where a high failure rate for companies is considered the norm. High priority for earlier stage companies is to secure funding with more dependence on external factors such as governmental support. The later stage companies, having access to product-derived funds, are more able to build internal resources and expand into global markets (Vanderbyl and Kobelak 2008).

The growth and success of biotechnology sector depends on a combination of good education, good science and good business (Moses 2003). Biotechnology education and bioentrepreneurship is a long-term issue requiring a long-term view; it should not be constrained by short-term funding (Swamidass 2008). The ability to take risks, prior work experience in private firms, and personal experience in cooperating with industry lead to a positive attitude towards switching to private sector employment or entrepreneurship (Fritsch 2010). However, despite numerous initiatives to popularize and sell science, it seems the attitudes and understanding of society towards science and scientists remain lower than expected. Scientists' communication in society comes forward as high priority and great importance (Baron 2010).

Emerging industries such as the life sciences, animal health, agricultural biotechnology and environmental products offer both a potential for economic growth and improvements in quality of life, the environment, and industrial productivity. Even governments in developing countries and investors are seeking to create and enhance biotech entrepreneurship face. Several enabling trends include increasing numbers of science graduates worldwide, accelerating pace of scientific advancement, dominating role of globalization enabling greater collaboration and the relentless competitive pressure to innovate (Thorsteinsdóttir et al. 2004, Thorsteinsdóttir et al. 2004). In times of current economic downturn, the number of life science companies is likely to decrease significantly. Nevertheless, policy agendas should focus on increasing factor conditions to enhance start-up formation, biotech clusters evolution, alliances, and skilled employment (Rezaie et al. 2009, Motar et al. 2004).

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