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AFIBIO Access to Finance in the Biotech Sector

Workpackage 1 – Identification and analysis of the biotech sector specificities relevant to access to finance

DELIVERABLE 1.1. Overview of the Biotech –Health Sector in Europe

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INTRODUCTORY REMARKS

AIMS

The Workpackage 1 aims at a better and common understanding of biotech-health sector specificities, in particular regarding access to finance (task 1.1.) and at identifying a limited number of model of case studies (task 1.2). The key findings and conclusions will enrich the debate during a Roundtable, held in Milano, the 30th of May, 2006, dedicated to exchanging experiences on the access to finance in the biotech-health sector.

The present deliverable (n°1.1.) is the starting point of the AFIBIO project, aiming at briefly describing the "countours" of the biotech sector in Europe from four point of view: industry, research base and financial sectors; and public policy support to the biotech.

The deliverable is divided into two parts:

- Synthesis at the EU level, including comments on the comparison with the USA performances
- National surveys

METHODOLOGICAL ASPECTS

The informations has been collected by the AFIBIO partners through the most available recent reports and studies, drafted under the umbrella of the national biotech associations or EU association. Statistics, web-based research, and personal contacts and interviews around Europe were also used by AFIBIO partners to compile such datas.

AFIBIO partners are aware that such a survey is more "empirical" than conceptual and scientific. Datas are not "harmonised" due partly to the fragmentation of the sector at the EU and national levels. Nevertheless the informations and facts collected are relevant for the AFIBIO objective which was during the first workpackage to capture a general overview of the sector over Europe.

DEFINITION

For the purposes of AFIBIO project, Biotechnology is defined as:

- the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services (OECD) and
- the integrated use of natural sciences and engineering sciences by the application of biosystems cells of microbial, plant and animal origin, parts thereof and molecular analogues in bioindustries", as defined by the European Federation of Biotechnology.

The project focuses on Biotechnology applied to healthcare.

An additional list of definitions is provided in annex 1

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OVERVIEW OF THE BIOTECH-HEALTH SECTOR IN EUROPE - SYNTHESIS

The following European synthesis is based on the short comments on the SWOT analysis included in each national survey following by a short EU-US comparison.

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1. SWOT Comments Synthesis: health and biotech sector in the countries covered by the study.

Country	Strengths	Weaknesses	Opportunities	Threats
Austria	Established networks and know-how regarding funding of start-up and growing life science companies Growing interest of VCs for the Life Sciences scene in the region Growing activities of the cluster organisations in international marketing (in cooperation with the companies) Dynamic life science scene	• young life science Cluster (first IPO in spring 2005)	Due to the aging population health related issues will continue to be top market opportunities (e.g. vaccines, anti-infectives, treatment of cancer) Political support with long lasting commitment for Life Sciences	Decreasing public money for health issues in Europe
Denmark	Good research conditions Good research centres and universities	Lack of established biotech industry Lack of experienced biotech business developers	Attachment to the strong cluster Medicon Valley	Success companies are taken over by national or international VC and oved out of the region
Estonia	Strong fundamental research base, while comparing the amount of R&D expenses with the results achieved in terms of scientific papers and impact factors the value is relatively high. Strong entrepreneurial spirit as about 30 spin-off / start-up companies have been created over the last few years.	very limited access to finance lack of management experience in development and running biotechnology businesses. lack of experiences in IP and lack of effective technology transfer structures	Based on the quality of basic research activities, potential attractiveness of investments and management competencies, making best use of the cost-effective business environment for the biotechnology development.	• The real risk is to "miss the train", i.e not being able to follow and catch up with global development in biotechnology both in RTD and business terms and as a result become marginalised and loose the critical mass of people and competencies to other countries and regions in the world.
Finland	The Finish biotechnology sector is ranked high in international competitiveness. Finland's biotechnology sector has evolved naturally out of a well-established biomedical research base, which has been supported by generous and committed public and private financing.	Researchers continue to experience problems in translating success at the bench into viable business opportunities. In particular, academic researchers have difficulty raising funding for the very early stages of starting up a company. Shortage of skilled management, in particular managers experienced in product development and business strategy within life sciences.	having more biotechnology companies than the USA, provides the means for healthy competition and cooperation. The European Commission has formulated strategies by means of which might catch up with the United States and continue a strong player on the international stage.	• In a perspective, the life sciences and biotechnology are moving forward at a fast pace. There is a question wether Europe will retain, improve or fall behind. Finland is part of Europe, and decisions made at the level of the European Union will strongly determine the future of the Finnish bioindustry.
France	• 3 rd European Country in Biotech,	Absence of clear industry leaders	Lot of support from the	

Country	Strengths	Weaknesses	Opportunities	Threats
	with a strong background in Chemical industry. • Concentration on Paris (Ile de France) especially when it comes to big money • A clear dynamics for creating new companies, but growing very slowly.	(a pyramid with a very wide base and a flat top). • not enough early-stage big money for ambitious discovery companies, which then turn to mixed models in order to generate steady income. • not enough Europe-oriented	government in terms of initiatives (YIC), though not enough initial investment.	
Germany	Strong government support Large network of universities, research institutes, clusters and associations involved in sector Growing use of biotech for industrial processes Increasing number of biotech patents	funding	Light increase in the number of partnership deals for commercialisation Progress in the number of new substances in Phase II and III Trend towards mixed business models Convergence of Bioregions could bring more strength to the sector Reduction in negative social perception of Biotech (mostly green biotech)	conditions need improvement, esp. tax issues • Few recent IPOs
Iceland	International business success ease with which specialist education and/or research can be applied in the real world in Iceland's close-knit society Small country, these include medicine and genetics, drawing on quality health-care services and unrivalled health and genealogical records among a homogenous population ¹	 improved economic situation in the 1990s and deCODE's success have greatly contributed to creating the biotech industry, but this success is consuming all of the country's scientists demographic conditions scarce trained people: only 7000 students(out to 270 000 inhabitants), of which less than 100 in biotech 		many biological and medical science students are now lured away from the university.

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¹ haemophilic bacteria in geothermal springs with high-temperature industrial applications and geological research such as geothermal prospecting and consultancy services

Country	Strengths	Weaknesses	Opportunities	Threats
	Unique resources for research.			
Ireland	Ireland has succeeded in attracting a large pharmaceutical manufacturing sector, employing 12,000 people in 80 companies. Of the present global pharma-products, an estimated 30 percent are of biotechnology origin or are related to biotechnology. The chemical industry is also important Pharma/chem is the second largest export sector in Ireland after engineering/electronic.	 No in house decision capacity No business "cluster" No national research projects: comment justifier cela: cela ne ressort pas de la fiche Irlande) 	With hundreds of million of dollars government investment, will Ireland's universities be able to produce scientific breakthroughs or will the country become simple a European manufacturing base?	• With hundreds of million of dollars government investment, will Ireland's universities be able to produce scientific breakthroughs or will the country become simple a European manufacturing base?
Israel	 Israel is expected to become a major centre for the development of pharmaceuticals, especially generic brands. Much better conditions for access to finance in Biotech, than in EU skilled and educated work forces, with more doctors, scientists and engineers per capita than any other nation close relationship between Israel and the US especially in terms of exchange of workforce and accessing high quality people. 	• However, in spite of recent growth, the Israeli pharmaceutical market remains relatively small and the Israeli biotechnology industry has yet to achieve the level of the development of its international competitors, particularly in the United States, Canada, Germany and the United Kingdom.	Effectiveness of the public support at least to initiate and provide adequate supporting and enabling an environment in favor for the creation of new companies	Relocation to the US
Italy	• Strong fundamental research activities: comparing the amount of R&D expenses with the results achieved in terms of scientific papers and impact factors the value are very high, in comparison too the rest of Europe and USA	 Quality of research is not converted in entrepreneurial activities: weak number of Companies and of employees the value of the turnover is lower to what is expected from the scientific results. 	 To take advantage of the quality of research to attract investors that will influence the mentality is a real opportunity. More industrial R&D, attracted by the quality of research, may generate more 	 The real risk is to lose the opportunity to fill the gap. If Italy will not achieve a bigger critical mass in its industrial biotech activities, if the industrial scenario will not be enriched by new start ups,

Country	Strengths	Weaknesses	Opportunities	Threats	
	High quality of scientific research as well as its overall costs	 Access to finance is a problem VC do not actually operate in Italy because of lack of critical mass. Lack of entrepreneurial mentality in the scientific community Lack of experience in IP and lack of structures for tech transfer available to help scientists in the valorization of their work. 	entrepreneurial mentality, more tech transfer specialists, and foreign VC operators may decide to set up offices in Italy, contributing to the generation of a positive milieu.	new success case histories, attracting the missing professionalities, then it will become even more peripheral, not connected, not intercepting the flow if international capitals and interests	
Latvia	The country's long experience and tradition, the availability of highly qualified specialists, cost efficiency, high competence in R&D and a strong manufacturing base are the factors that form an excellent foundation for business and innovative activities in Latvia's bio sector Brands that are recognized in the Latvian, Baltic, Russian and CIS markets is also a strength of the sector.	 Two typical gaps at present: preparation of the lacking study program and specialists, and transfer of technologies from the R&D sector into business. Lack of management and marketing capability necessary to capture western markets Lack of financial for new product approval for the Western markets Slow entrance of new specialists and ageing of senior researchers Limited market for the clinical tests Small local market and low purchasing power Weak local intellectual property protection framework Lack of risk capital funds for SME's and spin-off companies. 	Good access to existing large biotechnology centres in the Baltic Sea region The expansion of European Union has created a single market for medical devices and diagnostics spanning 28 countries (this is assuming that companies are able to meet labeling language requirements).	Companies must comply with CE marking requirements for the sale of medical devices in the EU. There exists a difficult recognition of Latvian products in Western markets and a limited international recognition of Latvian intellectual property authorities.	
Lithuania	Strong and long history and experience in biotechnology since 1975 when the All-Union Research Institution of Applied Enzymology (today Institute of Biotechnology) was created. The spin-off companies are relatively established, dating back to the end of '70s and '80s. Healthy local economic environment allow research companies to focus on their field of expertise.	The narrow field of expertise and small number of companies makes it hard to share knowledge Geographical distance from major biotechnology markets and research centres creates a cultural and cost gap. This also creates difficulties in collaboration and staying abreast of the newest development.	Lithuanian biotechnology companies are advanced and offer good investment opportunities. The companies and research institutions are successfully taking part in international projects and programs, including those funded by the EU. There is a considerable need for additional training of specialists and lecturers in these	Lithuanian accession to the EU has increased costs of labour for the companies.	

Country	Strengths	Weaknesses	Opportunities	Threats
Luxemburg	One of the largest financial sectors in Europe A big advantage for Luxembourg is the short way between companies and policy makers.	 Currently Luxembourg is no significant player in the Biotech segment. No history in life science 	fields. The sector can benefit from EU funds and UK education institutions that could offer specialized training for Lithuanian scientists. the government is supportive and the access to money may be easier than in other countries	
Norway	Robust basic research communities Relatively high degree of collaboration among entrepreneurs and between them and regional policy makers.	through an established university. Limited availability of seed and venture capital, few biotech venture companies and limited experience in biotech commercialisation Lack of political focus on dedicated innovation strategies. Lack of strategic information and cross-border collaboration in SMEs. Lack of experience management. Lack of direct inventions or experiences from other companies for startups. As a consequence, Norwegian companies tend to grow more slower than their international competitors. Lack of available in-house competence and resources for SMEs make it very difficult to approach and work within the European environment of legislation and regulation. Lack of communication between R&D and business communities	Great potential for increased innovation. Enterprises have a strong need for research-based knowledge. Biotechnological research and industrial development have a great future potential. Norway's close proximity to the rest of Europe opens the possibility for extensive cooperation with other Nordic countries, the rapidly growing markets of Eastern Europe and the countries of the EU. Blue biotechnology (marine) Difficulties to raise VC money but renewed optimism during the past few years and several listings on the stock market.	Oslo Teknopol: the life science cluster is small and the amount of new investment projects is not yet at a comparable international level. A majority of small companies depend on consultants and service providers. Risk that the enterprises technological opportunity window closes before they are ready to market their products.
Portugal	 biotechnology is relatively new in Portugal, there are not yet official economic data concentration in the Lisbon area and on human health care 	a very small number of companies lack of a VC industry, although in1999 something like €200 million where available from VC's to invest in new technology.		Marginalisation; small financial capacity

Country	Strengths Weaknesses		Opportunities	Threats
		 Business Angels are not organized, maybe not even existent. Investments into the biotech companies are still too few to support the sector, and come from public money 		
Spain	A significant number of enterprises involved in the life science sector (300),. Companies are located in the Barcelona and Madrid areas. Twenty-four percent of the companies have a strong R&D, product – or medical devices-oriented business model Research institutes in Barcelona and Madrid closed to the biotech clusters of firms	 Nevertheless only 24% (71) are completely dedicated to biotechnology, and the remaining are partially involved in biotech or/and are companies of service related to biotech industry Not sufficient critical mass included in terms of human resources ion the sector Business Angels are not organized. 	Plan for Scientific Research, Development and Technological	• small GDP investment rate in R&D (objective 1,4% in 2007, out to 3% of the Lisbon Strategy)
Sweden	 Sweden has a long pharmaceutical tradition, paired with an established financial and VC market, collaborations, major spinouts and world class science. Highest number of biotech companies per capita in the world. In Europe Sweden ranks fourth and globally ninth in the biotechnology sector. Even though most of the businesses are rather small, there is a spirit of collaboration in Sweden that benefits these young firms and their partners. Sweden is home to the fastest growing venture capital markets in the world, much of which has been dedicated to the life sciences industry. Sweden tops the list of industrialized countries in terms of investing the greatest proportion of their gross 	In most cases, the research findings of biotech companies are being commercialised outside Sweden.	Sweden can offer an internationally competitive environment for drug development. Sweden has various advantages as a setting for the modern genomics-based drug development work that is evolving from the mapping of genomes.	The challenge ahead will be to capture the full potential of Sweden's technical knowledge and combine it to take Swedish biotech to the next level in an increasingly competitive international environment. Today a number of countries have caught up with Sweden both in terms of the quality of medical care and investments in medical research.

Country	Strengths	Weaknesses	Opportunities	Threats
United Kingdom	domestic product in 'knowledge', defined as education, software and research spending. Sweden also has one of the most research friendly stem cell research legislations in the world. Swedish publications in clinical medicine are also the worlds most-cited, in relation to the population. 455 bioscience companies, employing 22,404 people and R&D employment of 9644 people. Cambridge, Oxford and Cardiff are the three main biotech areas Cambridge is the Europe's strongest bioregion in terms of research excellent and globally significant, many Nobel Prize winners. Existence of VC/Seed funds dedicated to the Biotech sector Merge and consolidation, Initiated in the UK and then	The UK biotech support sector has grown rapidly to more than Biotech, demonstrating the importance of biotech clusters on economic growth The early stage financing is limited and is a key constrain for technology transfer and exploration in market is slow. New structure strategy to accelerate the commercialisation is needed. In recent year the venture capital community has been invested fewer companies, although those tat do receive finance do get larger amount than previously.	National/regional programmes supporting Biotech research, companies and financing Biotech clusters	VC/Seed funds initiated in the UK and then move to US for development
	move to US for development	The big company focus more on development than discovery		

2. Key findings on the "SWOT Comments"

The sample of national overviews provides "findings", demonstrates similarities and disparities between the surveyed countries. Regarding the SWOT analysis, we have tried to have an EU vision classifying the findings under four items:

- 1. Enterprises/Clusters
- 2. Research institutes
- 3. Policy support through programmes
- 4. Finance: VC/Seed funds

2.1 <u>Enterprises/Clusters</u>

2.1.1 Strengths

A group of countries leads the biotech market in EU.

- It is constituted by UK, DE, FR, Israel, and in a lesser extent Sweden and surrounded by countries with a less business environment having nevertheless a lack of critical gap to appear on the international market;
- Italy, Spain, Austria, Norway and Denmark are part of this ring

2.1.2 Weaknesses

In terms of clustering for business sector, the principal weakness is the lack of critical mass, and a lack of culture of share and collaborative mind.

- In Italy, Estonia, Spain, Portugal, a structural weakness in term of commercialisation of the results of the research, hampered the creation of new start-ups; this is due to two main reasons: a lack of IPO skills, a lack of technology transfer structure
- Norway is experimenting a clustering initiative in different sectors, of which biotechnology is a hot priority, the biotech cluster (life science) located in the Oslo area is networking with other southern Scandinavian biotech clusters within a "Medcoast project". The initiative has been led by Oslo Teknopol to overcome the absence of tradition in sharing information, needs, projects and strategy within the entrepreneurs.

2.1.3 Opportunities

In general the surveyed countries outline the policy support to entrepreneurship as an opportunity. This is certainly very important but not targeted to biotech nor to access to finance issues.

Countries as Denmark, Germany, Ireland, Norway, Spain and France, have mentioned for instance public support focus on investment in university, on cooperation with Nordic countries, and on biotechnologies as a priority.

2.1.4 Threats

Some countries outlined as main threats the possibility to become peripherical due to a) the absence of critical mass, b) the attractiveness of US Business for their young companies which can be bought by US groups (the most successful obviously)

Estonia and Denmark are in such a situation

2.2 Research

2.2.2. Strengths

The leading countries for research are

- > UK, Germany and France, plus Israel, in spite of different contexts and different levels of success have good research units (see number of patents) UK has a successful track record in biotech and its linkage with the US scientific community is well known, as for Israel.
- ➤ Germany has Bioregio linked to research centres and business clusters; France has implemented Genopoles (in Grenoble and Ile de France) and "Competitiveness Poles" (5 are biotech-health –related, of which Nantes Atlanpole in the field of biotherapy)

2.2.3 Weaknesses

They are related to

- > the lack of a critical mass of skilled people: small number of students, technicians and researchers in the biotech sector (e.g. Estonia, Iceland, Spain),
- > Brain drain effect from more attractive countries (USA, Germany, UK)
- Lack of entrepreneurship culture among the researchers (e.g. France, Italy)
- > In Ireland R&D is done by companies coming from outside and doing research outside the country

2.2.4 Opportunities

For instance, there is no mention of the EU research programme for cooperation, nor in the literature, neither in the short descriptive frame provided by the AFIBIO partners related to their own cluster..

> Germany has mentioned as an opportunity the increasing number of biotech patents.

See exhibit below

Table 2: Patent applications to the EPO in 2002: Total (total number, AAGR 1997-2002, per million labour force and per million inhabitants), of which high tech (as a percentage), ICT (as a percentage) and biotechnology (as a percentage) at national level.

		Total			of which high		of which bio-
	Total number	1997-2002 AAGR	Per million labour force	Per million inhabitants	tech in % of the total number	of which ICT in % of the total number	technology in % of the total number
EU25	59 756	5.3	284.4	:	18.5	26.3	4.6
EU15	59 074	5.2	335.3	:	18.6	26.4	4.6
BE	1 452	2.9	333.5	140.8	18.8	22.3	6.9
CZ	122	11.7	24.1	12.0	6.2	13.6	1.1
DK	1 167	8.8	407.8	217.5	18.0	21.3	11.9
DE	24 514	5.0	618.5	297.4	15.0	22.7	4.2
EE	10	6.4	15.0	7.1	25.9	40.4	23.4
EL	109	11.0	23.4	9.9	20.1	16.7	7.8
ES	1 246	10.0	66.7	30.5	12.8	16.2	5.2
FR	8 556	4.4	327.0	144.2	21.4	29.3	4.0
IE	311	11.7	168.7	79.7	29.7	39.5	4.3
IT	4 747	6.7	198.1	83.3	10.1	14.5	2.4
CY	5	8.3	16.4	7.6	12.4	21.8	0.0
LV	13	6.9	11.4	5.5	19.3	27.0	7.2
LT	10	15.6	5.9	2.8	0.0	18.9	0.0
LU	69	4.4	355.6	154.6	5.6	12.9	1.9
HU	193	9.4	47.1	19.0	14.0	18.0	3.0
MT	5	9.3	29.2	11.8	0.0	49.9	0.0
NL	3 934	8.2	468.9	244.3	28.0	44.2	4.6
AT	1 483	6.7	384.6	183.9	14.6	21.8	3.8
PL	179	26.8	10.4	4.7	12.5	18.2	5.6
PT	49	15.9	9.1	4.8	7.8	37.3	2.2
SI	103	25.0	105.2	51.7	9.0	5.6	5.8
SK	41	14.4	15.9	7.7	10.3	6.5	14.1
FI	1 593	4.6	592.9	306.6	44.1	51.6	1.8
SE	2 587	-0.5	565.5	290.4	21.8	29.8	5.5
UK	7 258	5.3	250.8	:	22.5	31.1	6.7
IS	52	22.1	322.0	180.9	23.7	17.8	20.8
LI	28	6.6	:	849.8	5.3	7.6	3.5
NO	610	4.9	255.2	134.8	14.7	24.2	5.6
EEA18	59 764	5.2	:	:	18.5	26.4	4.6
EEA28	60 446	5.3	:	:	18.5	26.3	4.6
CH	2 987	4.8	731.4	411.7	13.1	21.4	4.5
BG	36	7.6	10.6	4.6	16.0	27.6	0.0
HR	87	30.5	48.8	:	6.3	10.9	2.3
RO	30	7.9	2.8	1.4	7.8	15.2	0.4
TR	118	31.6	4.9	:	8.8	7.9	2.6
CA	2 713	9.3	:	:	30.1	34.7	9.3
CN	1 480	43.6	2.0	:	32.7	35.3	7.3
JP	24 494	8.7	366.2	:	25.5	37.5	4.4
RU	591	5.3	8.2	:	12.3	17.7	5.1
US	46 819	6.1	319.9	:	29.8	34.4	6.5

Source: Eurostat, "Statistics in Focus – Science and Technology", 3/2006.

2.2.5 Threats

They are linked to the risk of

- ➤ Re-location of manufacturing companies,
- > and US capital invested in most successful start-ups with a departure of the start-up to the USA

2.3 Policy support through programmes

2.3.1 Strengths

- ➤ UK and Germany have specific Biotech programmes, France can be added with its Genopole's programmes (as mentioned above)
- ➤ Irish's support programme is focused on the improvement of Universities. The GDP rate invested in R&D is one of the highest in Europe (with Finland and Sweden)
- > Others countries have different type of support of which biotechnology is an issue

2.3.2 Weaknesses

There are not mentioned nor in the literature neither in the brief frame drawn by each AFIBIO partner.

- ➤ Nevertheless no policy scheme on finance is mentioned
- ➤ UK and Israel are offering a large portfolio of possibilities for companies in biotech sector and a range of VC, Seed, and equity finance at different stage of a firm.

2.3.3 Opportunities

The EU policies are not mentioned in the national surveys, but they can be considered as opportunities for all the EU countries, giving objectives and focus and additional money for projects

2.3.4 Threats

Even if they are not expressed, the main threats are coming from the international competition, in particular with the US

2.4 Finance

2.4.1 Strengths

In terms of access to finance there are **two mature markets**

Israel and UK have a developed biotech sector in terms of R&D capabilities and success through the commercial capacity of research, critical mass of companies (start-up and SMEs and bigger companies), internationalisation of their companies much more linked to US research and firms - this is obvious for the Israeli biotech sector -, and existing VC and Seed capital industry.

The biotech sector is supported by national and/or regional programmes in both countries. In the UK the early stage financing is limited and is a key constrain for technology transfer and exploration in market is slow.

- Sweden is home to the fastest growing venture capital markets in the world, much of which has been dedicated to the life sciences industry
- In Austria, there is a small market with skills on know how for funding of start-up and growing life science companies

2.4.2 Weaknesses

The other countries have some difficulties with a less mature market

- France, Germany, Italy and Norway are lagging behind in terms of volume of VC money available scoping early-stage
- > Spain, Portugal, Austria, Estonia, are prepared to build such a financial market nevertheless they can have specific problems: insufficient critical mass of companies, no business angels activity

2.4.3 Opportunities

The opportunities for establishing better conditions for a strengthen VC/Seed industry are not outlined by the surveys.

- ➤ Italy is a single example for sketching a scenario where better industrial R&D conditions, attracted by the quality of research, may generate more entrepreneurial mentality... and foreign VC operators may decide to set up offices in Italy. This is a rather pessimistic view of the situation.
- For the most structured biotech industries in EU countries, clusters represent an opportunity (see Cambridge model)

2.4.4 Threats

- For the UK biotech industry which has the most developed VC industries the US attractiveness is a real threat; VC companies could be absorbed by American funds, as well as dynamic innovative companies can be bought by American largest companies;
- In Ireland the scheme is a bit different as Ireland is less related to finance and as the risk is mainly to become a manufacturing area for north American companies (yet in the world market)

3. General conclusion

The EU Biotech Overview

- Tremendous potential of producing breakthroughs
- Internal and cross-border alliances and clustering continue to flourish
- Excellent University R&D
- Need for more leadership on all fronts
- Early stage funding critical for overall success, but still a problem.
- Increase in public company revenues.
- Trend to increased investor scrutiny.
- Lack of significant positive growth stories.
- Finding qualified business developers and managers with experience in the Biotech sector, or willing to come from big pharma currently difficult.
- Trend towards funding mixed business models.
- Difficulty translating research results into entrepreneurial activities.
- Product approval on the rise, but safety issues are becoming a challenge.
- VC more abundant in key locations, like Cambridge, Munich, Paris, etc.

Comparison with the USA performances

- Access to finance
- The US biotech landscape is older and more advanced developed than that of the European Union, and is also much more product oriented. European investors are also more risk averse than their US counterparts
- After the "bubble" in 2001, the private investment levels in Europe dropped significantly. Other considerations include the difficult tax and legal structures, and an entrepreneurial culture that lags behind the US. There are also fewer exit options for VC in the EU.
- Fragmentation is an issue: in the EU their are too many small companies, resulting in serious funding problems. There are also not enough listed companies to create a balanced portfolio for investors, who have moved towards companies with experience and in into later stages.
- The EU Biotech sector must focus on its strengths in order to find its place in the global supply chain. A cross-border stock exchange would therefore aid in consolidating Pan-European companies able to compete globally. European companies could also turn to US VC for funding.

NATIONAL SURVEYS

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AUSTRIA

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	AUSTRIA
1. General overview	
1.1. Enterprises	Number of enterprises About 150 SMEs. Many of these companies were founded as spin-offs by researchers from one of 13 Austria's universities active in life sciences. Since the late 1990s about 80 start-ups (focus red biotechnology) were founded, which form together with universities, research institutes and international companies a living Life Science community. In 2001, Austria's biotech firms joined to form Austrian Biotech Industry (ABI), which is part of the Association of the Austrian Chemical Industry (FCIO).
	Number of employees About 15.000 employees
	Sector Majority in the field of human medicine. In contrast to the concentration in red biotechnology, the plant and the environmental sector can be described as rather small.
	Business model
	Turnover rate 2bn € per year
	 Leaders Baxter AG; Boehringer Ingelheim Austria including the basic research centre Institute for Molecular Pathology, Vienna; Novartis AG including the Novartis Institute for BioMedical Research, Vienna; Sandoz GmbH; Eli Lilly including the Vienna School of Clinical Research (VSCR).
1.2. Research bases	Public / private expenditure
	 Main organisations Universities: Vienna is the second largest university town with 120 000 students at the nine universities. Five of these universities with 3800 fulltime scientists are active in all fields of life sciences. Together with excellent non-university research institutes such as the Novartis Institutes for BioMedical Research (NIBR) and Boehringer Ingelheim's Research Institute of Molecular Pathology (IMP) the universities form a perfect environment for high-tech companies. There is also a whole range of hospitals with Vienna's general
	hospital. Multinational enterprises such as Baxter, Boehringer

Ingelheim and Novartis as well as top-ranking biotech and medtech companies take advantage of this environment. Since 1998 around 50 biotech start-ups have been founded with most of these companies focusing on red biotechnology.

- Together with the big players on site these research oriented enterprises employ about 10.000 people.

Research fields of excellence

Universities: the medical field clearly dominates:

- cancer research,
- immunology
- dermatology.

1.3. Financial environment

Total equity investments

Types of funding

Life Science Austria provides pre-formation funding on favourable terms to allow for preparation of a technical proof of principle (pre-seed finance). Mezzanine loans allow for starting-up young biotech companies with an established technological foundation and high growth potential (seed financing).

Regional VC investments can then be backed by guarantees in Austria: as companies mature, Austria Wirtschaftsservice provides growth financing in the form of guarantees to finance business investments, and loans at competitive rates. Investors in Austrian biotech companies include Atlas Venture, Global Life Science Ventures (GLSV), EMBL Ventures, Mulligan BioCapital and TVM Life Science Ventures.

In addition, silent investments are very popular in Austria's biotech scene due to special tax reductions.

Austria has one of the lowest rates of business taxation in the EU. New group tax relieves allow international groups and companies with Austrian subsidiaries to transfer profits and losses between group subsidiaries and to reduce the overall corporate tax liability to a minimum. In addition to low tax rates, there are generous deductions and exemptions for investments in research and education. R&D allowances of up to 25% (in special cases up to 35%) are available on research and development expenditure. Companies not making profits can deduct a research premium of up to 8% of their research costs.

Success stories

Largest VC Funding Rounds in Austria:

- 29 M. € - Intercell AG, Vienna, January 2001

Global Life Sciences Ventures, Apax Partners, Nomura, TVM, NIB Capital, Star Ventures

- 30 M. € Igeneon AG, Vienna, August 2001
- 3i, Novartis Venture Fund, DVC, DB-Investor, Dresdner Bank, CBG, Commerz Beteiligungsgesellschaft, Capexit, Horizonte
 - 27 M. € Intercell AG, Vienna, July 2003

Apax, Nomura, TVM, GO Equity, Sal. Oppenheim, Alpinvest

- 27 M. € - Igeneon AG, Vienna, February 2004

Burrill & Co, 3i, DVC, Novartis Venture Fund, Capexit, gamma capital partners, Horizonte, Invest AG

- 11 M. € - Biovertis AG, Vienna, September 2004

TVM, Kapital & Wert

- 7,5 M. € - Fibrex Medical Inc., Vienna, March 2005

Global Life Science Ventures, Atlas Venture, EMBL Ventures, Mulligan BioCapital AG

- 10 M. € - Biovertis AG, Vienna, December 2005

TVM, Life Sciences Partners

- 42 M. € Nabriva Therapeutics Forschungs GmbH, February 2006 Nomura Phase4Ventures, Welcome Trust, HBM Partners, Global Life Science Ventures, Novartis Venture Fund.

Intercell Smart Vaccines

Japanese Encephalitis (phase III), therapeutic HCV vaccine (phase II)
Prophylactic vaccines and Therapeutic antibodies in the pipeline:
Staphylococcus aureus, Group A and B Streptococcus, traveller's

diarrhoea, Tuberculosis, Streptococcus pneumoniae

Since 1998 there has been three financing rounds: € 100 M. The third financing round closed in 2003 (€ 43 M.), it was the largest in Europe in 2003.

International investors: TVM, Nomura, Global Life Science Ventures, ... IPO in spring 2005.

Austrianova

Core technology: tailor-made gene delivery systems for new therapies of pancreas cancer, breast cancer, and other diseases.

Investor: Omni Technology Invest AG, Kapital & Wert – "atypische stille Beteiligung" –silent investments.

Recent successes:

July 2003 NovaCaps received orphan drug status by EMEA

End of. 2004 positive decision for phase III clinical study by EMEA, Start in Australia, 2006.

Biovertis

Intercell spin-off, winner of BOB Best of Biotech business plan competition 2002

Core technology: novel antibiotics to combat the threat of microbes resistant to available therapies

Recent successes:

In September 2004, it closed the first financing round up to € 10 M. Acquisition of Morphochem AG, second financing round 10 M. € December 2005; TVM, Life Sciences Partners.

Business Angels

1.4. Supportive and policy environment

National / regional support

Strong support from federal and regional authorities.

Programs

Life Science Austria — partner for scientists and companies:

LISA (Life Science Austria), the Austrian special purpose program acts as a central consultancy office and coordination centre for researchers and entrepreneurs. LISA is administrated by the federal bank Austria Wirtschaftsservice on behalf of the Federal Ministry of Economics and Labour.

- First point of contact for scientific evaluation of innovative ideas in the field of life sciences
- Consultancy for patenting and licensing, including introductions to patent agents and patent finance models
- Training, in the form of seminars and business plan competitions
- Assistance in starting a business and drawing up business plans
- Funding of start-up activities, such as proof of principle (prototyping), and cooperation with university business incubators
- Assistance in the start-up phase
- Funding in the form of national and regional grants and subsidies
- Introduction to investors through access to grant and funding networks
- Consultancy and network contacts for relocation projects
- Providing of infrastructure
- Networking events

Clusters

Tyrol is Austria's second most important biotech region with some 3,000 people working in 45 companies related to life science. A further 2,300 researchers work in bioscience at Tyrolean universities, including the Leopold-Franzens-University Innsbruck, the Innsbruck Medical University and the newly founded private University for Health Sciences, Medical Informatics and Technology (UMIT). The Tyrolean research fields of cell engineering, implant- and implantation technology, medical device, health- and bioinformatics, bioanalytics and drug delivery are internationally established.

Tyrolean life science companies benefit from the academic know-how. For example, the AlcaSynn Pharmaceuticals company develops opioid receptor blockers for use in pain therapy. The company Thiomatrix utilizes thiolated polymer systems for mucosal delivery of biomolecules like polypeptides, whereas Innovacell deals with the development of new cell therapy processes to replace damaged muscle tissue. The health informatics company Icoserve designed an advanced image management software solution for hospitals.

The Tyrolean Future Foundation works to promote and develop life science in the region. It promotes the Competence Centre Medicine Tyrol where 111 researchers and entrepreneurs are currently collaborating on a total of 19 projects. From the very beginning, the Tyrolean Future Foundation also supported the CAST-Center for Academic Spin-offs Tyrol, the HITT-health information technology tyrol and the ACBT-Austrian centre of biopharmaceutical technologies.

In Styria the biotech scene is quite small but very dynamic. Two Grazbased companies, i.e. Oridis and ProtAffinhave won Best of Biotech's Central European business plan award for life science two years in a row. Oridis was founded by the Medical University Graz, and concentrates on identifying molecular targets to use in the treatment of diseases. ProtAffin, a Karl-Franzens University spin-off, develops genetically modified proteins for the treatment of inflammatory diseases. JSW Research, also based in Graz, develops transgenic animal models for the study of neurodegenerative diseases. Graz is also very renowned for being home to the Kplus Research Center for Applied Biocatalysis. White biotechnology and upscaling technologies are rapidly growing in the Styrian region. Companies like VTU Engineering Ltd., Lactosan Ltd. and Zeta Holding are major players in the region. Total healthcare solutions, including testing facilities are offered at the ZMF (center for medical research) to their partners for clinical trials (phases 1-3). Since recently life science in Styria is strongly supported by « human.technology.Styria ».

Associations

2. SWOT Comments

Strengths

- Established networks and know-how regarding funding of start-up and growing life science companies
- Growing interest of VCs for the Life Sciences scene in the region
- Growing activities of the cluster organisations in international marketing (in cooperation with the companies)
- Dynamic life science scene
- Political support with long lasting commitment for Life Science

Weaknesses

- Young life science Cluster (first IPO in spring 2005)

Opportunities

- Life sciences are a high risk business with enormous potentials with long and cost-intensive development cycles
- Due to the aging population health related issues will continue to be top market opportunities (e.g. vaccines, anti-infectives, treatment of cancer)

Threats

- Decreasing public money for health issues in Europe

DENMARK: the Biotech and Medical Technology sector in the region of Aarhus Drafted by which partner?? and Aarhus Biotech Cluster

Some developments on the Medicon Valley could be added DENMARK	
1. General overview	DENNIARK
	Number of entermises
1.1. Enterprises	Number of enterprises
	Number of employees
	Approx. 150
	Sector
	- Biotech
	- CRO
	- Medical Devices
	- Bioinformatics
	Business model
	Turnover rate
	Approx. 20 M. Euro
	rippion. 20 M. Euro
	Leaders
	- Borean Pharma A/S
	- AROS Applied Biotechnology ApS
	- BSP Pharma A/S
	- Senetek plc
	- Danish Myo Technology A/S
	- Nordisk Røntgen Teknik A/S
12.5	- CLCBio A/S
1.2. Research bases	Public / private expenditure
	Approx. 40 M. Euro
	Main organisations
	University of AarhusAarhus University Hospital
	- University College of Aarhus
	Research fields of excellence:
	- Functional genomics
	- Bioinformatics
	- Bio Nano
1.3. Financial environment	Total equity investments
	15 M. Euro
	Types of funding
	- Existence of VC/Seed funds dedicated to the Biotech sector
	o 1 Seed fund
	0 1 VC
	- Types of funding
	o Seed, development
	- Types of companies funded (products, services, mixed,

	medical technologies):
	o Borean Pharma A/S
	 Cobento Biotech A/S
	o CellCure ApS
	 ReceptIcon ApS
	Success stories
	Business Angels
	Organized
1.4. Supportive and policy environment	National / regional support
	Programs
	National/regional programmes supporting Biotech research,
	companies and financing: Seed funding
	Clusters
	Clusters
	Clusters Associations
2. SWOT Comments	Associations
2. SWOT Comments	Associations BioMedico Forum
2. SWOT Comments	Associations BioMedico Forum Strengths
2. SWOT Comments	Associations BioMedico Forum Strengths - Research
2. SWOT Comments	Associations BioMedico Forum Strengths - Research Weaknesses
2. SWOT Comments	Associations BioMedico Forum Strengths - Research Weaknesses - Lack of established biotech industry
2. SWOT Comments	Associations BioMedico Forum Strengths - Research Weaknesses - Lack of established biotech industry - Lack of experienced biotech business developers
2. SWOT Comments	Associations BioMedico Forum Strengths - Research Weaknesses - Lack of established biotech industry - Lack of experienced biotech business developers Opportunities
2. SWOT Comments	Associations BioMedico Forum Strengths - Research Weaknesses - Lack of established biotech industry - Lack of experienced biotech business developers Opportunities - Attachment to the strong cluster Medicon Valley Threats - Success companies are taken over by national or
2. SWOT Comments	Associations BioMedico Forum Strengths - Research Weaknesses - Lack of established biotech industry - Lack of experienced biotech business developers Opportunities - Attachment to the strong cluster Medicon Valley Threats

ESTONIA

Drafted by the Institute of Baltic Studies

	ESTONIA
1. General overview	
1.1. Enterprises	Number of enterprises Around 30, some of them have R&D as their core business while most of them are developing their own service and/or products. They are all relatively small, most of them still in the spin-off and start-up phase.
	Number of employees The biggest companies employ today around 30 people and the smallest start-ups only 1-2 persons. The Total number of employees is around 150.
	Sector
	Business model
	Turnover rate The estimated total turn-over of the sector was 10 M. € in 2005.
	Location Almost all Estonian biotech companies are located in Tartu and Tallinn
	Leaders / success stories
1.2. Research bases	Public / private expenditure It is unfortunately not possible to get exact figures about public and/or private R&D expenditure dedicated to biotechnology. However a rough calculation based on the total R&D budgets of those institutions listed above allows to estimate a total spending of up to 30 M. € on RTD in biotechnology in Estonia in 2005.
	 Main organisations Biomedical Engineering Centre of Tallinn University of Technology Centre of Excellence for Gene and Environmental Technologies Centre of Excellence for Molecular and Clinical Medicine Estonian Agricultural University Estonian Biocentre Institute of Gene Technology of Tallinn University of Technology Institute of Molecular and Cell Biology of University of Tartu Institute of Technology of University of Tartu Jõgeva Plant Breeding Institute National Institute of Chemical Physics and Biophysics

- Estonian Genome Project Foundation

Research fields of excellence

- Biochemistry
- Bioinformatics
- Cell biology
- Evolutionary biology
- Functional genomics
- Genebanks
- Genetics and Proteomics
- Microbiology and virology
- Molecular biology
- Oncogeneses
- Plant physiology

1.3. Financial environment

Total equity investments

Annual equity investments into biotech in Estonia is very small, estimated to be 2-3 M. € per annum.

Types of funding

There is not one single specialised biotech Venture Capital Company and no special VC/seed funds dedicated to the biotech sector in Estonia. Existing seed funding comes mainly from the Central Government entrepreneurship promotion instruments and there are no regional or local seed capital instruments available yet in biotechnology field.

Success stories

Business Angels

Estonian Business Angels are not very active in biotechnology, being much more dedicated to the manufacturing and service sectors.

1.4. Supportive and policy environment

National / regional support

Biotechnology has been one of the 3 key development priorities for Estonian RTD policy since 2002. Estonian Biotechnology foresight was carried out 2003-2004 providing inputs for the Estonian National Biotechnology Strategy currently under preparation and expected to be ready by autumn 2006.

On the regional basis the Tartu region has prepared within the Tartu Regional Innovation Strategy an action plan for biotechnology development in the regions which focuses on bringing more foreign investments into biotechnology, developing regional cluster of biotechnology companies, providing support for export activities of biotechnology companies and finally developing a modern research infrastructure. Total investment of 10 M. € was foreseen for the period 2005-2008.

Programs

Clusters

In terms of clusters, 2 biotechnology micro clusters could be identified in Estonia - one which has emerged around Tartu University and another one which has emerged around Tallinn University of Technology. However there are no special biotechnology Cluster Initiatives launched yet in those regions. In terms of business support organisation, the Tartu Biotechnology Park, Tartu Science Park and Tallinn Technology Park provide incubation and business development services for biotechnology companies.

Associations

The main interests of Estonian Biotechnology Sector are represented by Estonian Biotechnology Association which includes both companies and academic research institutions and is the main lobby organisation for biotechnology in Estonia. It is also member of EuropaBio.

2. SWOT Comments

Strengths

- Strong fundamental research base when comparing the amount of R&D expenses with the results achieved in terms of scientific papers and impact factors the value is relatively high.
- Strong entrepreneurial spirit exists as about 30 spin-off / start-up companies have been created over the last few years.

Weaknesses

- Very limited access to finance
- Lack of management experience in development and running biotechnology businesses.
- Not enough qualified business development and management resources available.
- Lack of experience in IP
- Lack of effective technology transfer structures are clear weakness

Opportunities

- Based on the quality of basic research activities it will hopefully be possible to attract more investments and management competencies into Estonia making a best use of the cost-effective business environment for biotechnology development.

Threats

- The real risk is to "miss the train", i.e not being able to follow and catch up with global development in biotechnology both in RTD and business terms and as a result become marginalized and lose the critical mass of people and competencies to other countries and regions in the world.

FINLAND

Drafted by the Institute of Baltic Studies

	FINLAND
1. General Overview	
1.1. Enterprises	Number of enterprises 128 private and 2 public biotechnology companies (according to Scanbalt) 154 companies (according to Finish Bioindustries FIB) Ranking six in Europe, approximately 10% of all European biotechnology companies are located in Finland. Most are small and medium sized, specialized in innovative niche areas. Approximately half of the small and medium sized companies were founded after 1997. Some companies belong to bigger multinational corporations.
	Number of employees Approximately 1700 people with a great majority of the enterprises employing up to 50 people.
	Sector
	Business model
	Turnover rate 141 M. € in 2001.
	Location
	Leaders / success stories
1.2. Research bases	Public / private expenditure
	 Main organisations A. I. Virtanen Institute for Molecular Sciences, University of Kuopio BioCity Turku Biomaterial Graduate School, University of Helsinki Faculty of Biosciences, University of Helsinki Faculty of Chemical Engineering, Abo Akademi University Faculty of Natural Sciences, Abo Akademi University Finnish Genome Centre, University of Helsinki Functional Foods Forum, University of Turku Helsinki University of Technology Institute of Biomaterial, Tampere University of Technology Institute of Biotechnology, University of Helsinki Institute of Environmental Engineering and Biotechnology, Tampere University of Technology Lahti Polytechnic

- Lappeenranta University of Technology
- Ragnar Granit Institute, Tampere University of Technology
- Research areas of pharmacy and natural sciences faculties, University of Kuopio
- Swing Life Science Center
- Turku Centre for Biotechnology
- University of Oulu

There are five major biotechnology centres in Helsinki, Kuopio, Tampere, Turku, Oulu and in addition there are universities and research centres in other towns.

There is high collaboration between companies and academic researchers in Finland but aproximateply 30-40% also cooperate with researchers abroad. Finland's strategy is to concentrate on areas in which it has a strong research base — pharmaceuticals, diagnostics, biomaterials, functional foods and enzymes.

Research fields of excellence

- Biochemistry
- Bioinformatics
- Biopharmacy
- Biotechnology
- Cell biology
- Cell metabolism
- Cell signalling
- Genetics
- Gene transfer
- Immunology
- Membrane technology
- Molecular biology
- Molecular medicine
- Pharmacology
- Plant physiology
- Protein modification
- Structural biochemistry

1.3. Financial environment

Total equity investments

Life sciences received 40 M. € funding during 1999, and funding has been growing at about 20–30% per year for the past three years.

Types of funding

There are multiple venture capital companies that are specialized in seed, start-up or late stage funding. Almost all start-up funding for biotechnology companies in Finland comes from venture capital. The research and development costs of small and medium size companies was 114 M. € in 2001.

There is also a public funding company Sitra (The Finnish National Fund for Research and Development) for seed, start-up or late stage funding. Sitra is an independent public foundation under the supervision of the

	Finnish Parliament.
	Success stories
	Business Angels
1.4. Supportive and policy environment	National / regional support
	Programs The rapid rise of the Finnish biotechnology sector can be traced back to the national technology programs of the 1980s.
	Clusters
	Associations The Finnish Bioindustries FIB is Finland's biotechnology industry association, established in 1997. It is a private, independent non-profit organisation that promotes national and international networking and information transfer between the different players in the field. Finnish Bioindustries participates in national and international technology programs, actively exploits finance systems and promotes technology transfer. One of the main tasks is to help the work of commercializing new areas of biotechnology.
2. SWOT Comments	 Strengths The Finish biotechnology sector is ranked high in international competitiveness. Finland's biotechnology sector has evolved naturally out of a well-established biomedical research base, which has been supported by generous and committed public and private financing.
	 Weaknesses Researchers continue to experience problems in translating success at the bench into viable business opportunities. In particular, academic researchers have difficulty raising funding for the very early stages of starting up a company. Shortage of skilled management, in particular managers experienced in product development and business strategy within life sciences.
	 Opportunities Europe, as a region, having more biotechnology companies than the USA, provides the means for healthy competition and cooperation. The European Commission has formulated strategies by means of which might catch up with the United States and continue a strong player on the international stage.
	Threats - In a perspective, the life sciences and biotechnology are moving forward at a fast pace. There is a question wether Europe will retain, improve or fall behind. Finland is part of Europe, and

decisions made at the level of the European Union will strongly
determine the future of the Finnish bioindustry.

FRANCE

Drafted by Nantes Atlanpole

	FRANCE
1. General overview	TRANCE
1.1. Enterprises	Number of enterprises
	225 companies
	Number of employees
	9000 employees
	Sector
	Business model
	27% service providers
	29% product development
	44% Contract research (France Biotech)
	Turnover rate
	1944 M. € total revenue
	Location
	➤ In Nantes Atlanpoles
	37 biotech companies, 28 of which in healthcare.
	12+ support companies (IP, business development, marketing,
	biocomputing, consultants).
	4 pharmaceutical companies (SMEs with ability to commercialise
	pharmaceutical products). No big pharma.
	They are active in Biotherapies (Gene therapy, Cell therapy,
	Immunotherapy, Biomaterials, Tissue engineering – bone) and
	Genetics/Genomics (fingerprinting – High-Thoughput DNA analysis)
	Leaders / success stories (in Nantes area)
	LFB, Transgene, Eurofins Scientific (Nantes), Cerep, Flamel, Genfit,
	Biogemma, Idenix, Nicox, Trophos, IDM.
	Vivalis (Nantes), IGNA (Nantes)
1.2. Research base	Public / private expenditure
	608 M€ R&D expenditures in Biotech
	The transport of the state of t
	Main organisations Notice and recognition (INSERM, CNRS, CEA)
	National research institutes (INSERM, CNRS, CEA)Institut Pasteur
	- Institut Fasteul - Institut Curie
	INSERM Transfert, subsidiary of INSERM, has a dedicated team to advise
	the researchers and promote tech transfer. They are able to take shares in the
	companies created from the patents. They are about to create a new seed
	fund.
	CNRS is less specifically involved in life science.
	The IP belongs to the academic institution the researcher and the lab belong

to (a bit complicated, because of frequent multi-partners (INSERM personnel in a joint CNRS-University research lab...). From '99 on, it is possible for a researcher to take up to 15% shares in a company created from his IP.

Academic IP are in the hands either of the Universities who generally do not have any strategy for commercialisation, or of the public research institutes who tend to organize for a more efficient approach of licensing.

No real commercialisation activity from the universities, better performance from INSERM with its subsidiary INSERM Transfert who can also take shares in the start-ups when outlicensing the IP. They are about to launch a seed fund as well.

➤ In Nantes Atlanpole

University of Nantes (incl. Medical faculty), National Veterinary School and also, University of Angers.

Cancer Research Institute (only French INSERM label), Institute of Transplantation, Thorax Institute, Gastroenterology Research Institute.

Nantes University Hospital, 2 National Cancer Centres (combined patients inclusion potential number 2 in France), also Angers University Hospital.

Research fields of excellence

- Cancer (National Effort),
- Infectious diseases and immunology (Institut Pasteur),
- Cell and Gene Therapy (Genethon and Nantes),
- CNS.

1.3. Financial environment

Total equity investments

Total Equity investments in Biotech were 167 M€, ofwhich

Venture Capital 90 M. €

Private placements 1 M. €

Public Equity Offering 52 M. €

Types of funding

According to the national VC association (AFIC):

107 VCs can invest in Biotechnology

Of which 18 at the seed stage (Ouest Ventures and Pays de Loire Développement in Nantes)

Types of funding²

Seed: VERY difficult, but possible through arrangements between local/regional instruments on small money. In 2004 and 2005, only 5 companies found seed money from the above mentioned VCs.

First round : 15 companies/year, easier access, but very centralized around Paris.

The trend is oriented towards financing sustainable companies (those who generate a minimal income through service). At the national scale, a recent failure in raising funds was Entomed (Strasbourg).

Money raised by French biotech companies : VCs = 80% (20% in the US)

There seems to be a moving trend when it comes to which kind of business

-

² Source, France Biotech

model is easily funded... The trend at the moment is favourable to mixed models (service + product development). VCs tend to face difficulties with the valuation of tech platforms.

Success stories

Business Angels

See France Angels, member of EBAN. In addition various individual BAs invest in a biotech company not affiliated to any association whatsoever.

> In Nantes Atlanpole

The companies needing a single initial investment and no subsequent refinancing succeed in finding money from the VCs (Atlanbio, IGNA) Investments in the cluster 2002/2003/2004/2005 compared to federal overall life science investments with private equity: overall less than 10M. €. 2 national VCs invested in Nantes: Créago and Rotschild.

1 regional fund: Pays de Loire Développement (max. 150.000 €) invested in 5 companies.

The companies are financed less than half a year, up to 1 year, 1-2 years or more than 2 years.

Very low burnt-rate for the companies: generally mixed models generating income through services while developing their own products.

CV Vaccum:

TcLand had to find money from local Bas and generate income from their discovery platform to develop their own molecules. No possibility to attract VCs.

Vivalis has created Créago on board but also an industrial investor preventing VCs from being interested.

VCs got interested in IGNA and Atlanbio when they realized that these service companies (bio-analysis for forensics and pharma) were generating strong income. It was too late. No good evaluation for these types of companies.

Drain to US stock exchange not applicable. There is only Eurofins Scientific, born and raised in Nantes, IPO in '97 on the Nouveau Marché (Paris).

1.4. Supportive and policy environment

National / regional support

- French national Innovation agency (Oséo-ANVAR)
- National contest for company creation (Ministry of Research)
- Young Innovative Company status

(incl. Research Tax Credit)

Around 80 M€ direct public incentives in 2003

Programs

Clusters

5 main Clusters in Biotech and Health (Pôles de Compétitivité) Paris, Lyon, Strasbourg, Nantes, Toulouse.

Associations

France Biotech is the main national Biotech Association

	Also Retis, the national network for innovation, has a special interest for
	Biotech SMEs.
2. SWOT Comments	Strengths
	- 3 rd European country in Biotech, with a strong background in Chemical
	industry.
	- Lots of support from the government in terms of initiatives (YIC,),
	though not enough initial investment.
	Weaknesses
	- Very Paris-centred especially when it comes to big money
	- A clear dynamics for creating new companies, but growing very slowly.
	- Very strong support to enhance company creation, but not enough money
	to make them ambitious
	- Absence of clear industry leaders in Biotech (a pyramid with a very wide
	base and a flat top, groups of 10-15 year old companies with 100 employees each).
	- Not enough early-stage big money for ambitious discovery companies,
	which then turn to mixed models in order to generate steady income.
	- No exit for VCs on the market, meaning weak ROI and impact on the
	perception of Risk
	- Even public-funded funds (BIOAM) were reluctant to invest heavily at
	seed stage (though apparently changing a bit)
	- Not enough Europe-oriented
	- Difficult cohabitation between a VC and an Industrial investor (Vivalis
	in Nantes): different strategies for the company.

GERMANY

Drafted by Heildelberg Technologie Park

	GERMANY
1. General overview	
1.1. Enterprises	Number of enterprises 538 Biotech companies
	Number of employees 11958 employees (According to the Federal Statistical Office)
	Sector
	Business model - Product Development, 31% - Service Providers, 19% - Service and Product, 50%
	Turnover rate 1030 M. €
	 Leaders / success stories BASF, Roche Diagnostics, Bayer Diagnostics, Abbott, Merck Large SMEs: Astra Zeneca, Aventis Pasteur, Baxter, Becton Dickinson, Biofrontera, Brain, Cellzome, DeveloGen, Epigenomics, Evotec OAI, GPC Biotech, Jerini, MediGene, MorphoSys, Paion, Qiagen, Rentschler, Scienion, SunGene, Teraklin, Wilex
1.2. Research bases	Public / private expenditure The Federal Ministry of Education and Research has awarded € 1.03 Bn since 1998 for R&D support in the Biotech sector. In those projects within academic Institutions or SMEs, around € 320 M. was covered by private capital.
	 Main organisations German Research Association (DFG) Fraunhofer Society Hermann von Helmholtz-Association of Research Centers Max-Planck Society Scientific Society Gottfried Wilhelm Leibniz
	Other Research Institutes - German Cancer Research Center (DKFZ), Heidelberg - European Molecular Biology Lab (EMBL), Heidelberg - German Collection of Microorganisms and Cell Cultures (DSMZ), Braunschweig
	Research fields of excellence - Pharmaceuticals,

	- Diagnostics,
	- vaccines,
1.3. Financial environment	- industrial processes.
1.3. Financial environment	Total equity investments € 548 M. in 2004
	€ 346 M. From Venture Capital
	€ 42 M. came from IPOs
	€ 270 M. from Follow on and other offerings.
	Types of funding
	Biotech firms in Germany are funded mostly by venture capital, much
	of which comes from foreign investors. State funding plays little more
	than a supplementary role. Examples of VCs dedicated to Biotech are TVM, Global Life Science, Heidelberg Innovation.
	Setup (8%), Start up (72%), Scale up (20%)
	200sp (6/6), 20m2 sp (20/6)
	Success stories
	57% of the companies funded develop drugs based on their own
	technology platform. For example, Cellzome is a privately held drug
	discovery company building a R&D pipeline in chronic diseases, with a primary focus on Alzheimer's disease. In March 2003 the company
	completed its Series C funding at an amount of approx. € 30 M. In the
	second half of the year the company entered into two partnerships with
	pharmaceutical companies, Johnson & Johnson PRD and Bayer
	HealthCare.
	Pusings Angels
	Business Angels Business Angels: Organised around the Business Angels Netzwerk
	Deutschland.
1.4. Supportive and policy	
environment	The BioRegion concept has proven successful so far and will continue
	to be supported by the government. Other recent examples are the "Bio
	Chance", "BioChancePlus", "BioProfile", "BioFuture" and
	"HighTechFoundationFund" programs, which help individuals or
	groups or research scientists to start up their own company.
	Programs
	Federal Ministry of Education and Research (BMBF), Federal Ministry
	of Economics and Technology (BMWi), German Research Association
	(DFG), German Environment Federal Foundation (DBU), German
	Academic Research Service (DAAD), Stifterverband for die German
	Wissenschaft, Industrial Research Foundation, Alexander von
	Humboldt- Foundation, Körber-Foundation Klaus Tschira Foundation (KTS), Fritz Thyssen Foundation, Peter and
	Traudl Engelhorn Foundation, Schering-Foundation, Volkswagen
	Foundation, Alzheimer Research Initiative (AFI), German - Israeli
	Foundation for Scientific Research and Development (GIF), German-
	American Fulbright-Programm, Robert-Bosch-Foundation, Industrial
	Research Center Association (AiF).

Clusters

Biotech clusters (Bioregions):

·NanoBioNet Saarland-Rheinland-Pfalz ·BioRegion Hessen

·BioTOP Berlin-Brandenburg

BioRiver® ·biosaxony Sachsen

·BioLAGO Konstanz

·BioRegionUlm

·BIO Mitteldeutschland Sachsen- ·BioRegion Rhein-Neckar-

Anhalt

·Bio-Tech-Region Lippe

·BioCon Valley Mecklenburg- Marburg

Vorpommern

·Bioinitiative Nord:

Biotechnologie in Holstein

Bremerhaven/ Bremen

·BioPark Regensburg

·BioRegion Hamburg: TUTech ·BioMedTec Franken

Innovation GmbH

·BioRegio STERN Management

·BioRegion Frankfurt: Bio Tech Alliance

·BioRegio Freiburg BioValley

·BioRegio Jena Thüringen

·Bioregion Köln/Düsseldorf

·BioRegion Maas-Rhein-Dreieck

·BioRegioN Niedersachsen

Dreieck

Ostwestfalen ·BioTech-Region Munich

·Initiative Biotechnologie

 $\cdot Landes Gesells chaft$ **BIOPRO**

Baden-Württemberg

Schleswig- ·Life Science Agency Nordrhein-

Westfalen

·BioNord: Biotechnologiestandort ·Life Technologies Ruhr

·Nanobioanalytik Münster

·Netzwerk Life Science Bavaria

·Norgenta NordDeutsche Life

Science Agentur

Associations

·DECHEMA Society for

Chemical Technology and Biotechnology, Frankfurt

·German Botanic Society c/o

Humboldt-University Institute for Biology.

·German Society for Biomedicine GFP Bonn

Technology in VDE - Frankfurt

·German Society for

experimental and Pharmacology and Toxicology Molecular biology

DGPT, Mainz

c/o Herrn Prof. Dr. Ulrich

Hengge University Skin Clinic Chemistry. Göttingen Düsseldorf.

·German Society for Hygene and ·Society Microbiology (DGHM)

·German Society for DNA-Repair Research ·European Molecular Biology Organization EMBO.

Heidelberg

Berlin. Association for Promotion of private German Plant Breeding -

·Society of German Chemists

GDC, Frankfurt

clinical Society for Biochemistry and - GBM

Frankfurt

·German Society for Gene Theray ·Society for Development Biology MPI for biophysical

·Society for Genetics,

for Plant Breeding,

c/o Göttingen

Institute for Hygene and ·Society for Virology, Münster Microbiology. Würzburg ·Society for Cell- and Tissue German Society for Immune Engineering (GZG), genetics (DGI) Großenkneten Section of the European Tissue ·German Society for Immunology Culture Society (ETCS). Mainz c/ o Med. University Lübeck, ·Union of German Biologist and Institute for Microbiology and bioscientists Societies. Munich ·Union of Hygiene. Lübeck bioscientist and German Society for Proteom biophysicians Societies. Frankfurt Research c/oMax Planck Union of German Engineers, Biochemistry. Area of Expertise: Biotechnology. Institute for Martinsried Düsseldorf ·German Society for ·Society for General and Applied Regenerative Medicine Frankfurt Microbiology. Frankfurt Cell Society for the Promotion of ·German Society for Biology, German Cancer Human Genome Research, Berlin Researchs Center. Heidelberg ·German Cancer Society, Frankfurt

2. SWOT Comments

Strengths

- The German biotechnology industry occupies the number one position in Europe concerning the number of biotechnology companies with a potential for development (346 companies).
- Strong government support
- Large network of universities, research institutes, clusters and associations involved in sector
- Growing use of biotech for industrial processes
- Increasing number of biotech patents

Weaknesses

- Unfavourable law on gene technology
- Difficulties for private companies in establishing partnerships
- Lack of sufficient early phase funding
- Large translation gap from basic research to products

Opportunities

- Light increase in the number of partnership deals for commercialisation
- Progress in the number of new substances in Phase II and III
- Trend towards mixed business models
- Convergence of Bioregions could bring more strength to the sector
- Reduction in negative social perception of Biotech (mostly green biotech)

Threats

- General Framework conditions need improvement, esp. tax issues
- Few recent IPOs
- Relocation of successful SMEs
- Long development and approval cycles
- Low acceptance of green biotech endangers future growth capability

AFIBIO – Access to Finance in the Biotech Sector Priority 2004-FP6-INNOV-6 Research and Innovation Contract number n°022560 WP1 - Deliverable 1.1. Overview of the Biotech-Health Sector in Europe

ICELAND

Drafted by Cardiff University

	ICELAND
1. General overview	
1.1. Enterprises	Number of enterprises 2000 – 5, ; 2002 – 10 ; 2006 – 11.
	Number of employees 2001 in biotech firms: 919 (only in business enterprise sector) and R& D employment of 374 in 1999.
	Sector
	Business model
	Turnover rate 2005: 15 bn ISK (only in business enterprise sector). Turnover in medicinal and medical products has been growing over the years and in 2003, the total value of exports of medicinal and medical products was ISK 13,500 M Icelandic firms are now world leaders in prosthetic devices and important exporters of diagnostic technology and medical software. These firms have pioneered medical software for doctors and pharmacies to manage and dispense prescription drugs. Diagnostic technology to assess and measure sleep disorders, respiratory problems and geriatric symptoms have also been developed in Iceland
	Leaders / success stories The primary focus of deCODE's business is to identify the genetic causes of common diseases and to apply this information to develop new drugs and DNA based diagnostics. Built upon an understanding of the basic biology of human disease, these products are aimed at diagnosing and counteracting the underlying biological mechanisms of disease, not just the signs and symptoms.
	Iceland Genomics Corporation (Icel. UVS) is a privately owned cancer biology company founded in 1998. The company uses an innovative 'clinical genomics' approach to understand the underlying mechanisms of cancer, isolate and characterize new therapeutic targets for cancer, and assess outcomes of specific therapies in genetically defined subcategories of cancer patients. IGC's competitive advantage is based on the combination of a genetically favourable population, extensive sample collections with associated clinical data, access to family pedigree data and a sophisticated bioinformatics effort that can cross-correlate all of this valuable information to drive discovery. IGC is seeking collaborations and partnerships with academic labs, pharmaceutical and biotechnology companies that are seeking to

Sector in Europe

accelerate their cancer discovery and improve their drug development process.

BioCule (Lifeind) is a university start-up company founded in December 2000 in collaboration with the University of Iceland and the National University Hospital. BioCule is an R&D company focused on genetic technology.

The company's main purpose is to develop and market novel methods to detect and isolate polymorphisms, mutations, and lesions in complex DNA samples such as human DNA. The original incentive was the need for powerful methods for genetic research on complex diseases in Iceland. These methods, however, have worldwide applicability in various types of genetic research. They are therefore being marketed internationally.

Primex is focusing mainly on marine biotechnology, specifically production and supply of biopolymers and proteins from marine sources.

Being among the largest suppliers of chitin-derived biopolymers in the western hemisphere, Primex is actively involved in development projects focusing on advancing chitin based technologies into various fields of applications, such as materials, cosmetics and biomedicine. Primex is co-ordinating three European CRAFT projects focusing on food and biomedical applications of chitosan.

NimbleGen Systems, Inc. develops DNA microarray and chemistry technologies, providing the highest density arrays available in the industry in a fraction of the time of conventional microarrays. NimbleGen, with headquarters in Madison, WI, is a spin-off of the University of Winsconsin - Madison and retains several patents on its unique technology. The company draws on technical expertise from molecular biology, genetics, organic chemistry, clinical pathology, engineering, physics and bioinformatics services gained through experience with industry leaders.

Prokaria is a biotechnology company that uses proprietary ecological enrichments and bioinformatics to directly discover novel genes in nature. Prokaria provides access to the Icelandic biosphere in terms of geothermal biodiversity. In order to develop new catalysts and small bioactive molecules Prokaria uses in silico screening and rational molecular evolution to create and develop new applications for research, industry and medicine.

1.2. Research bases

Public / private expenditure

In 1999, the R&D expenditure in Biotechnology was about 3.4 bn ISK.

Main organisations

	- University of Iceland
	- The Iceland University of Education
	- Reykjavik University
	- Marine Research Institute
	- Warme Research Institute
	Research fields of excellence
1.3. Financial environment	Total equity investments
	Types of funding International producers, marketing companies or distributors have increasingly been investing in Icelandic high-tech companies, and several of Iceland's most progressive ventures have announced plans to list their shares on overseas stock markets.
	Success stories Many of the growth leaders in Iceland today are specialized small or medium-size enterprises with expert staff targeting ultra-specialized technology niches where, in many cases, they rank with world leaders in their fields. In Iceland there are more than 700 highly-qualified and well-educated people working in the field.
	Business Angels
	National / regional support
environment	
	Programs
	Clusters
	Clusters Reykiavik BioCluster:
	Clusters Reykiavik BioCluster: Reykjavik is becoming a North Atlantic cluster of exciting
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	Clusters Reykiavik BioCluster: Reykjavik is becoming a North Atlantic cluster of exciting companies in the field of Biotechnology and Medical Science. The project ranges from producing valuable enzymes from fish, using genetically altered barley for the pharmaceutical industry to identifying the genetic causes of common diseases and developing new drugs and DNA based diagnostics. For the past decade IceTec has been a major player in the field of biotechnology in Iceland. The institute, in cooperation with others, operated Biotechnology House that among other things housed IceTec's biotechnology department. Based on work conducted
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	Clusters Reykiavik BioCluster: Reykjavik is becoming a North Atlantic cluster of exciting companies in the field of Biotechnology and Medical Science. The project ranges from producing valuable enzymes from fish, using genetically altered barley for the pharmaceutical industry to identifying the genetic causes of common diseases and developing new drugs and DNA based diagnostics. For the past decade IceTec has been a major player in the field of biotechnology in Iceland. The institute, in cooperation with others, operated Biotechnology House that among other things housed IceTec's biotechnology department. Based on work conducted there the company named Prokaria (see above) was formed. In addition to Prokaria the institute has also participated in creating the following companies: Genís, Íslensk fjallagrös, Sprett, Feyging and most recently, in cooperation with the Agricultural Research Institute, Orf Genetics, in connection with the Biotechnology
	Clusters Reykiavik BioCluster: Reykjavik is becoming a North Atlantic cluster of exciting companies in the field of Biotechnology and Medical Science. The project ranges from producing valuable enzymes from fish, using genetically altered barley for the pharmaceutical industry to identifying the genetic causes of common diseases and developing new drugs and DNA based diagnostics. For the past decade IceTec has been a major player in the field of biotechnology in Iceland. The institute, in cooperation with others, operated Biotechnology House that among other things housed IceTec's biotechnology department. Based on work conducted there the company named Prokaria (see above) was formed. In addition to Prokaria the institute has also participated in creating the following companies: Genís, Íslensk fjallagrös, Sprett, Feyging and most recently, in cooperation with the Agricultural Research Institute, Orf Genetics, in connection with the Biotechnology Centre at Keldnaholt.
	Clusters Reykiavik BioCluster: Reykjavik is becoming a North Atlantic cluster of exciting companies in the field of Biotechnology and Medical Science. The project ranges from producing valuable enzymes from fish, using genetically altered barley for the pharmaceutical industry to identifying the genetic causes of common diseases and developing new drugs and DNA based diagnostics. For the past decade IceTec has been a major player in the field of biotechnology in Iceland. The institute, in cooperation with others, operated Biotechnology House that among other things housed IceTec's biotechnology department. Based on work conducted there the company named Prokaria (see above) was formed. In addition to Prokaria the institute has also participated in creating the following companies: Genís, Íslensk fjallagrös, Sprett, Feyging and most recently, in cooperation with the Agricultural Research Institute, Orf Genetics, in connection with the Biotechnology

field are endless, for example in the pharmaceutical, chemical and food industries. IceTec will utilise the diverse expertise of its employees to develop projects with practical applications in consultation with companies and the scientific research community in Iceland and abroad.

Associations

2. SWOT Comments

Strengths

- Icelandic companies have already proved themselves able to compete successfully at the international level in the health and biotech sector, taking advantage of the ease with which specialist education and/or research can be applied in the real world in Iceland's close-knit society.
- In several important fields, unique resources for research.: medicine and genetics, drawing on quality health-care services and unrivalled health and genealogical records among a homogenous population; haemophilic bacteria in geothermal springs with high-temperature industrial applications and geological research such as geothermal prospecting and consultancy services. Both the Geothermal and Fisheries Training Programmes of the United Nations University are located in Iceland.
- The improved economic situation in the 1990s and deCODE's success have greatly contributed to creating the biotech industry.

Weaknesses

- This success is consuming all of the country's scientists. With its population of only 270 000, finding trained personnel is a larger problem for Iceland than, say, for Finland or Ireland with respectively 5.17 and 3.8 M. citizens. The whole of the University of Iceland has only 7000 students, and fewer than 100 embark on a biology course each year—in 2001, the Department of Biology had a record number of 70 new students.

Opportunities

Threats

 The private sector is able to offer more highly paid positions, the number of trained scientists in academia is shrinking since many biological and medical science students are now lured away from university.

IRELAND

Drafted by Cardiff University

	IRELAND
1. General overview	
1.1. Enterprises	Number of enterprises 41 bioscience companies
	Number of employees Employing 2940 people and R&D employment of 1053 people (2003) ³ In 2005, the companies in biotech-related sectors account for 12% of Ireland's manufacturing employment and 26% of manufacturing sales.
	Sector Eight of the world's Top Ten of the pharmaceutical industry have plants or subsidiaries in the country. 125 pharmaceutical companies active in Ireland as a European manufacturing base. 15 of the world's 25 largest manufacturers of medical devices have production facilities in Ireland.
	Business model
	Turnover rate € 982 M. in 2003. Export of drugs and active pharmaceutical ingredients worth € 29bn.
	Location
	Leaders / success stories Elan Corp., Biotrin, Tridelta, Megazyme, AGI therapeutics, Opsona Therapeutics, Deerac Fluidics
1.2. Research bases	Public / private expenditure Total R&D expenditures dedicated to Biotech in Ireland was € 277 M. in 2003.
	 Main organisations The National University of Ireland University College Dublin Dublin City University Trinity College, Dublin University College Cork
	Research fields of excellence

³ Source, EuropaBio, 2005

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1.3. Financial environment

Total equity investments

€198 M.,

Venture Capital: € 1M., Private placements: € 7 M.

Public Equity Offering: € 189 M. in 2003.

Types of funding

The investment into the biotechnology companies are possible through government support strategy scheme.

Success stories

Amgen, the world biggest biotechnology company announced to invest \$ 1 bn in Ireland for its major new development and manufacturing (2006).

Business Angels

From 1st September 2005, the Dublin Business Innovation Centre (DBIC) is managing the database of individuals, or "Business Angels", with funds to invest in small and medium enterprises.

1.4. Supportive and policy environment

National / regional support

The Irish biotech industry has been one of the main components of the country's thriving economy, underpinned by enthusiastic government support (The Irish Biotechnology Investment Programme).

The government support the international networks such as TechLink UK-Ireland and BioLink USA-Ireland.

Programs

Ireland biotechnology program is focused, in large part, on investing in the country's university research programs and infrastructure.

From 2000 to 2006, Ireland plans to invest US\$ 2.45bn in research and technology; US\$ 309M. shall be funnelled to biotech projects through the Forsight Fund.

Clusters

- Dublin Cluster (International)
- Cork Cluster
- Galway Cluster
- Maynooth Cluster
- Tallght Cluster

Associations

Irish BioIndustry Association (IBIA) was established in 1998. Its primary mission is to support the development of a biotech sector in Ireland. in an active participant in the Technology foresight exercise which gave rise to the establishment of Science Foundation Ireland (SFI), with consequent prioritisation of biotech.

2. SWOT Comments	Strengths
	- Ireland has succeeded in attracting a large pharmaceutical
	manufacturing sector, employing 12,000 people in 80 companies.
	1
	- Of the present global pharma-products, an estimated 30% are of
	biotechnology origin or are related to biotechnology.
	- The chemical industry is also important in Ireland.
	Pharma/chem is the second largest export sector in Ireland after
	engineering/electronic.
	Threats
	With hundreds of M. of dollars of government investment, will
	Ireland's universities be able to produce scientific breakthroughs or
	will the country become simple a European manufacturing base?

ISRAEL

Drafted by which partner?

	ISRAEL
1. General overview	
1.1. Enterprises	Number of enterprises More than 200 companies including about 40 incubator projects. Three quarters of the companies are small start-ups with less than 20 employees while a dozen companies represent 80% of the total market value of the industry, generate two thirds of sales and employ about 50% of the industry's workforce. In the last decade, the number of companies increased by an average of 17% per year, while the sales generated by the sector grew by 27% per year.
	Number of employees Approx. 4000 employees.
	Sector The majority of the companies focus on biopharmaceuticals. Pharmaceutical and diagnostics firms represent 72% of the Israeli biotechnology industry, agricultural biotechnology accounts for 20%, and the remainder includes veterinary and environmental applications. Product development for cancer, auto-immune syndromes and neurology disorders and to a lesser extent, on food, cosmetics and environmental products. About 50% of university research projects in therapeutics and 66% of biotech drugs in the pipeline are in the areas of auto-immune diseases, neurology and cancer.
	Business model
	Turnover rate Estimated at \$2.3bn in 2003. Investments in Israel were estimated at \$1.2 bn. Furthermore, by 2010 Israel is expected to account for 3% of the global biotech market.
	Leaders / success stories The Israeli biopharmaceutical industry prides itself on generating products such as beta Interferon developed by InterPharm, Copaxone developed by Teva, human growth hormone and Biolon developed by Biotechnology General (BTG).
	The two main producers and importers of biopharmaceuticals are Teva Pharmaceutical Industries, and Agis Industries which together have a combined market share in Israel of 50%-60%. Other major biotechnology companies in Israel include Biotechnology General (BTG), Pharmos, Interpharm (IPL) and Compugen.
1.2. Research bases	Public / private expenditure National expenditures on civilian R&D in Israel rose 164% to NIS 23.8 bn in 1990-2004. The R&D expenditure share of GDP rose from 2.8% to 4.6% in Israel during the period 1996-2004, compared to a much smaller and

hardly growing R&D expenditure share of GDP in the US, EU-15, Ireland or Finland

Main organisations

Seven universities, five technical colleges and ten specialized research institutes engaged in advanced biotechnological research. An estimated 35% of all academic scientists in Israel work in the life sciences field and spend 40-50% of all academic research funding.

Research fields of excellence

1.3. Financial environment

Total equity investments

Types of funding

Israeli VCs are structured in a similar pattern to their US counterparts; namely, limited partnerships with the venture capital firm serving as the general partner and the investors as the limited partners. The fund has a predetermined life horizon (usually10 years) and operates as a closed fund with fixed capital. The relationships between the general partner and the limited partners may vary from one fund to another, but, in principle, the general partner is entitled to a management fee and shares in the capital gains that may accrue as a result of a successful exit of a portfolio company.

Israeli VC's enjoy certain tax benefits provided they meet a number of prerequisite conditions set by the government.

Distinctive Features of Israel's VC Industry:

Highest VC investments as a share of GNP and High Share of VC investments are 'Early Phase': This contrast with European VC/PE industries where 6% of annual European VC investments were early phase while 46% were MBO/MBI (see PWC 2003).

A substantial share of VC entrepreneurs with S&T backgrounds and with high tech experience - many if not most VC and PE entrepreneurs in Europe have financial backgrounds rather then S&T backgrounds or High Tech experience.

90% of funds coming from foreign sources - this contrasts with the US where the share of foreign investors in capital raised during 1995-99 was 3% (OECD 2000)

Negligible investments by domestic Pension Funds – only 0.1-0.2% of the Israeli Pension Funds & Insurance Company's assets are investments in VCs (OECD 2003) which contrasts with between 3-5% in the US and Europe.

Other Characteristics: LP form; a strategy directed to early phases; a large pool of SU; and the highest number of IPOs in NASDAQ after the US and Canada.

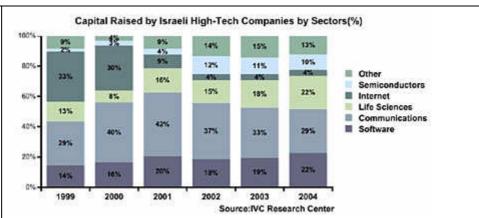
The VC industry co-evolved with high tech, particularly the SU segment of high tech industry - as during consolidation of Silicon Valley's tech cluster around the SU Semiconductor companies (who where to a large extent VC backed) during the early 70's. This was the period of emergence of the US VC industry (AKT, 2004).

1997	1998	1999	2000	200)1	2002	2003	2004
Capital								
Invested in								
Israeli SU	440	589	1,011	3,092	1,985	1,138	1,011	1,465
VC as % of GDP	0.4%	0.5%	0.9%	2.6%	1.7%	1.0%	0.9%	1.2%
Domestic VC	0.470	0.570	0.570	2.070	1.7/0	1.070	0.970	1.2/0
Investments	260	334	436	1270	812	481	421	665
in Israeli SU								
Domestic								
VCs								
investment	- 0				44			
as a share of	59%	57%	43%	41%	41%	42%	42%	45%
total								
investments in Israeli SU								
Israeli Se								
Canital Investe								
Capital Illveste	a in isr	aeli stai	rt-ups b	y stages	:			
1997	20 m 1sr 1998	aeli stai 1999	rt-ups by 2000	y stages 2001	:	2002	2003	2004
1997 Capital	1998				:	2002	2003	2004
1997 Capital Invested in	1998	1999	2000	2001				
1997 Capital Invested in Israeli SU	1998 440				1,985	2002 1,138	2003 1,011	2004 1,465
1997 Capital Invested in Israeli SU Seed as % of	1998	1999 589	2000	2001 3,092	1,985	1,138	1,011	1,465
1997 Capital Invested in Israeli SU Seed as % of total	1998 440 10%	1999	2000	2001				
1997 Capital Invested in Israeli SU Seed as % of total Early as % of	1998 440 10%	1999 589 5%	2000 1,011 5%	2001 3,092 10%	1,985 5%	1,138 2%	1,011 6%	1,465 8%
1997 Capital Invested in Israeli SU Seed as % of total Early as % of total	1998 440 10% 56%	1999 589	2000	2001 3,092	1,985	1,138	1,011	1,465
1997 Capital Invested in Israeli SU Seed as % of total Early as % of total Mid as % of	1998 440 10% 56%	19995895%53%	2000 1,011 5% 52%	2001 3,092 10% 38%	1,985 5% 41%	1,138 2% 35%	1,011 6% 32%	1,465 8% 24%
1997 Capital Invested in Israeli SU Seed as % of total Early as % of total Mid as % of total	1998 440 10% 56%	1999 589 5%	2000 1,011 5%	2001 3,092 10%	1,985 5%	1,138 2%	1,011 6%	1,465 8%
1997 Capital Invested in Israeli SU Seed as % of total Early as % of total Mid as % of total Late as % of	1998 440 10% 56% 15%	1999 589 5% 53% 31%	2000 1,011 5% 52% 28%	2001 3,092 10% 38% 30%	1,985 5% 41% 32%	1,138 2% 35% 54%	1,011 6% 32% 49%	1,465 8% 24% 56%
1997 Capital Invested in Israeli SU Seed as % of total Early as % of total Mid as % of total	1998 440 10% 56%	19995895%53%	2000 1,011 5% 52%	2001 3,092 10% 38%	1,985 5% 41%	1,138 2% 35%	1,011 6% 32%	1,465 8% 24%

^{*} Seed – technological feasibility (firm age up to 1 year); Early – Alpha and Beta products (firm age up to 3 years); Mid – Initial sales (firm age up to 5 year); and Late – Revenues growth prior to Exit (firm age up to 8 years). Investments in late stages are insignificant in Israel and are not included in the VC investment statistics.

The major sectors that attracted investment during Q3/2004 were: communication - 28%; life sciences and software - 21% and 18%, semiconductors 13% and internet companies only 2%.

Capital Raised by Israeli High-Tech Companies by Sector:



The above shown data presents quite a clear picture of Israeli VC/PE industry patterns of investment during the last 8 years. On average 54% of the investments in Israeli start-ups were by foreign VC companies; the rest investments of Israeli VC companies (foreign investors were also the dominant source of capital of Israeli VC companies). Seed investment was on average 6% which is a very high figure compared to 1% in the U.S. and even less in Europe (VentureOne statistics). 78% of the capital invested in Israeli SU during the period was early stage and mid stage finance (as defined by EVCA terms); while that of late stage i.e. prior to an IPO was 16%. Moreover, the share of early stage finance decreased while that of mid stage finance increased through time.

Success stories

Business Angels

1.4. Supportive and policy environment

National / regional support

The Ministry of Science, Culture and Sports and the Office of the Chief Scientist (OCS) of the Ministry of Industry and Trade supports the Israeli biotech industry by providing long-term financial support for research and development (R&D) projects to biotech companies, enhancing cooperation between academia and industry to ward the commercialisation of Israeli biotechnology worldwide, by encouraging international strategic cooperation and by assisting start-ups through a variety of support activities including incubators.

Programs

Creation of the OCS: Grants to Private Sector R&D

The Horizontal Grants to Business Sector R&D program began with the creation at the Ministry of Industry and Trade of a specialized agency, the Office of the Chief Scientist (OCS). This program was and continues to be the backbone of the country's R&D/Innovation strategy. Until the early 1990s, more than 90% of OCS disbursements to Civilian R&D came from this program, which supports the R&D activity of individual companies oriented to new/improved products and processes directed to the export market.

New innovation and Technology Policy Programs:

- Inbal: a Government owned Insurance company, which gave partial (70%) guarantees to traded VC funds. Four VC companies were established under Inbal regulations. The early VC support program failed to create VC industry.
- Magnet Program: a 360M a year Horizontal Program supporting cooperative, generic R&D involving two or more firms and at least one University.
- Technological Incubators: a program supporting entrepreneurs during the Seed Phase, for a period of three years. The incubators are privately owned and managed. Noth they and the projects get financial support from the Government.

Critical Dimensions of YOZMA Program Design:

- Fund of funds and direct investments in SU; Favored LP type of VC company.
- A focus on Early Phase investments in Israeli high tech Start-up companies
- 10 privately owned Israeli VC funds each managed by a local management company (formal institution) and involving Reputable Foreign Financial Institution (annually a VC/PE Management Company)
- Government participation in each fund 8 M. dollars (up to 40% of fund's capital)
- String incentive to the "Upside" a 5 years option to buy the Government's share at cost
- Privatisation of Yozma Fund & Program
- The Yozma program triggered a strong process of collective learning and attracted professional VC agents into the program

Clusters

Associations

2. SWOT Comments

Strengths

- One of the world's most skilled and educated work forces, with more doctors, scientists and engineers per capita than any other nation.
- Expected to become a major centre for the development of pharmaceuticals, especially generic brands.
- Lower costs for conducting clinical trials and a history of bringing new products to an advanced stage of development more rapidly than anywhere else in the world, makes Israel an attractive place for foreign companies to conduct clinical trials or establish research partnerships. In comparison to other European countries access to finance for the Biotech sector the conditions in Israel are much better mainly due to the effectiveness of public support at least to initiate and provide adequate supporting and enabling an environment in favour for the creation of new companies.
- In addition there is a close relationship between Israel and the US especially in terms of exchange of workforce and accessing high quality people.

Weaknesses

- The Israeli market is dependent on imported goods. The pharmaceutical market, including generic drugs, was valued at \$1.5 bn in 2002, 50% of which were imported drugs
- ,The Israeli pharmaceutical market remains relatively small and the Israeli biotechnology industry has yet to achieve the level of the development of its international competitors, particularly in the United States, Canada, Germany and the United Kingdom.

Opportunities

- Israel's biotechnology industry still has not reached its full potential
- The challenge for the industry is to move to the next phase of growth in which it nurtures more broadly based companies, supported by the physical, regulatory and scientific infrastructure necessary for long term growth.

ITALYDrafted by Milano San Raffaele Science Park

	ITALY
1. General overview	22.22.2
1.1. Enterprises	Number of enterprises 102 enterprises.
	Number of employees The number of employees is around 1500 in the 29 main biotech companies, while the total number of employees is around 5000.
	Sector
	Business model Only 29% of them have R&D as their core business (main biotech companies), while the remaining are service or commercial entities. 29% of the companies have a strong R&D, product – or medical devices-oriented business model, while the remaining 71% have a service business model.
	Turnover rate €1.1 bn (2002).
	Location 55% of the main biotech companies are located in the Lombardy Region.
	Leaders / success stories Only three companies are public (Novuspharma was bought by Cell Therapeutics Inc. in 2003; Biosearch Italia merged with Versicor in 2002, creating Vicuron; finally, NicOx is a French-Italian biotech company), and no more Italian. Other important leaders are MolMed, BioXell, Axxam, Primm.
1.2. Research bases	Public / private expenditure It is difficult to get clear figures about public and/or private R&D expenditure dedicated to biotechnology. For sure, 15% of the total turn-over of the sector are reinvested in R&D (€165 M.) every year. In the Progetto Metadistretti, the Lombardy Region allocated €10M for biotech projects for 2005. Foundations play an important role in biotech, and in the last five years they funded around 2000 biotech projects with an investment of almost €500 M
	Main organisations - San Raffaele Research Institute (Milan) - Istituto FIRC di Oncologia Molecolare (IFOM-Milan) - Istituto Europeo di Oncologia (IEO-Milan) - Istituto Superiore Sanità (Rome) - Mario Negri (Bergamo) - Istituto Nazionale Tumori (Mlan)

- Bioindustry Park Canavese (Turin)
- Area Science Park Trieste (Trieste)

Research fields of excellence

- Cardiovascular Diseases
- Oncology
- Infectious and Neurodegenerative Diseases
- Transplants and Organ pathologies (Stem Cells and Tissue Replacement Therapy)
- Immune System Diseases (Allergic or Hypersensitivity Diseases)
- Molecular Medicine and Genetic Diseases (Molecular Diagnosis, Gene and Cell Therapy, Pharmacogenomics and Pharmacogenetics)
- Biobanks

1.3. Financial environment

Total equity investments

Annual equity investments in biotech are, on average, around €15 M./year, mainly derived from VCs. The three IPO companies were able to raise €382 M. in the period 1997-2003.

Types of funding

There are no VC/seed funds dedicated to the biotech sector, VCs specialized in life science operating in Italy are mainly foreign.

Seed funding are mainly from the Central Government and local institutions. Foreign VC's enter in the development and exit stages.

Success stories

MolMed was founded in 1996 as a spin-off of the San Raffaele Scientific Institute. MolMed's mission was initially to supply services and processes related to patient-specific *ex-vivo* cell manipulation in accordance with Good Manufacturing Practices. In 2001-2002 MolMed raised € 13.4 M. from VC, while in 2004 the company raised €20 M. from Italian private investors, changing the business model from a fee-to-service to a product company.

Business Angels

Business Angels are organized (IBAN-Italian Business Angels Network), but they are not very active in biotechnology, being more dedicated to the manufacturing sector.

1.4. Supportive and policy environment

National / regional support

The Lombardy Region has created – first region in Italy to do so – its own financial tools to participate in the venture capital funding of new companies, particularly for medium-sized companies, small companies, start-ups and spin-offs. Some of the funds allocated account for a total of €85 M., to be added with €20 M. backing. Aiming atincreasing resources, a Framework Programme Agreement for technological innovation has been signed with the Ministry of Industry. This has led to €41 M. already made available to Lombardy companies. The Lombardy Region has also set up an important relationship with the European Commission, presenting a number of important projects within the 6th Framework Programme. For biotechnology, the Lombardy Region had a budget of

€10 M. for 2005.

Public investors, primarily the Ministry of Research and University (MIUR) and the European Union Funds fill the gap between the beginning of an enterprise and the financing from VC's. For example, the 29 main biotech companies received a total of €40.35 M. inthe 1996-2002 periods (in particular, €.96 M. from EU, €0.5 M. from the Lombardy Region and €38.89 M. from MIUR).

Programs

Clusters

The only real biotech cluster is located in the Lombardy Region (5 science parks, 5 universities, 50% of Italian biotech companies). Discussions are going on about the creation of a biotech cluster in the North East of Italy.

Associations

2. SWOT Comments

Strengths

- Strong fundamental research activities: comparing the amount of R&D expenses with the results achieved in terms of scientific papers and impact factors the value are very high, in comparison to the rest of Europe and USA.
- The intrinsic quality of scientific research as well as its overall costs are a strength point.

Weaknesses

- Such good quality of research is not converted in entrepreneurial activities: the number of companies, of employees and the value of the turnover is lower to what you may expect from the scientific results.
- Access to finance is one of the reasons, because VC do not actually operate in Italy because of lack of critical mass.
- Lack of entrepreneurial mentality in the scientific community.
- As a consequence, lack of experience in IP and lack of structures for tech transfer available to help scientists in the valorisation of their work.

Opportunities

- Take advantage of the quality of research to attract investors that will influence the mentality
- More industrial R&D, attracted by the quality of research, may generate more entrepreneurial mentality, more tech transfer specialists, and foreign VC operators may decide to set up offices in Italy, contributing to the generation of a positive milieu.

Threats

- Lose the opportunity to fill the gap.
- If Italy does not achieve a bigger critical mass in its industrial biotech activities, if the industrial scenario is not enriched by new start ups, new success case stories, attracting the missing professional potentials, then it will become even more peripheral, not connected, not intercepting the flow of international capitals and interests.

LATVIADrafted by the Institute of Baltic Studies

	LATVIA
1. General Overview	
1.1. Enterprises	Number of enterprises The number of companies involved in the life science sector is around 30. This is less companies then there were in 1990, but then there is a positive tendency that in the past 5 years. Alongside with the great companies, a number of SME and spin-off companies have been developing very successfully.
	Number of employees Overall the biopharma production and service sector employs around 3730 specialists. About 50% of the employees work in the production of pharmaceuticals and medicines sector.
	Sector
	Business model
	Turnover rate The overall industrial output of the biopharma sector in 2002 was 70 M. €, which is 0.81 % per cent of the GDP. The pharmaceutical sector is the most advanced in the bioindustry and has the most significant output (38.2 M. €). Main export markets are Baltics, CIS and Western countries to a less extent.
	Location
	Leaders / success stories Major companies are Grindeks, OlainFarm and MedPro, all of them producers of generic pharmaceuticals and intermediate pharmaceutical products.
1.2. Research bases	Public / private expenditure
	 Main organisations A.Kirhensteins Institute of Microbiology and Virology, University of Latvia Bio-medical Research and Study Centre, University of Latvia Institute of Biomedical Engineering and Micro Technologies, Riga Technical University Institute of Experimental and Clinical Medicine, University of Latvia Institute of Microbiology and Biotechnology, University of Latvia Institute of Organic Synthesis Research Centre "Sigra", Latvian University of Agriculture State Plant Breeding Station "Priekuli"

Research fields of excellence **Biochemistry Bioenergetics** Bioengineering Bioorganic chemistry Biotechnology Cytology Genetics Immunology Microbiology Molecular biology Physiology **Pharmaceutics** Good study programs in the universities are ensured in the fields of organic synthesis, pharmacy, biomaterials and biomechanics, medicine and genetics. Weak or nonexistent study programs in the fields of food, agriculture, environment, and wood biotechnologies. 1.3. Financial **Total equity investments** In 2001 the total state funding of the research and development activities environment was 34 M. € (0.44% of GDP). Types of funding Three main financing sources of Latvian biosector R&D and education are: central government funding, own assets and external sources of financing. About half of all the expenditure of the R&D is financed by the government within the framework of the "Science" program. There are only very few venture capital companies operating in Latvia that invest in biotech. They mainly prefer late stage funding. Amount of attracted foreign direct investment in the whole biosector, including services and trading, is modest - about € 20 M., of which manufacturing absorbed about € 7.6 M. (40%). **Success stories Business Angels** Supportive National / regional support and There is a general National Innovation Concept that determines the policy environment development of research in Latvia up to 2010, but no specific life sciences developmental concepts. **Programs** Clusters Associations

At the moment the Biopharma sector is fragmented from the

	organizational point of view - there are several associations of sub-
	branches operating in this sector, yet no common organization of the
	sector.
2. SWOT Comments	Strengths
	 The country's long experience and tradition, the availability of highly qualified specialists, cost efficiency, high competence in R&D and a strong manufacturing base are the factors that form an excellent foundation for business and innovative activities in Latvia's bio sector Brands that are recognized in the Latvian, Baltic, Russian and CIS markets is also a strength of the sector.
	Weaknesses
	- Two typical gaps at present: preparation of the lacking study program and specialists, and transfer of technologies from the R&D sector into business.
	- Lack of management and marketing capability necessary to capture western markets
	- Lack of financial for new product approval for the Western markets
	- Slow entrance of new specialists and ageing of senior researchers
	- Limited market for the clinical tests
	- Small local market and low purchasing power
	- Weak local intellectual property protection framework
	- Lack of risk capital funds for SME's and spin-off companies.
	Opportunities
	- Good access to existing large biotechnology centres in the Baltic Sea
	region
	- The expansion of European Union has created a single market for medical devices and diagnostics spanning 28 countries (this is
	assuming that companies are able to meet labeling language requirements).
	Threats
	- Companies must comply with CE marking requirements for the sale of medical devices in the EU.
	- There exists a difficult recognition of Latvian products in Western
	markets and a limited international recognition of Latvian intellectual property authorities.

LITHUANIA

Drafted by the Institute of Baltic Studies

	LITHUANIA
1. General Overview	
1.1. Enterprises	Number of enterprises There are several private biotech companies in Lithuania. Most on them are spin-offs from the Institute of Biotechnology, some of them began operating as early as 1975. The sector is not significant in terms of size, but some companies are targeting world-class industry player. Some companies share resources with research institutes. Many enterprises collaborate with foreign companies and research organizations and some have become part of larger multinational companies.
	Number of employees Biggest companies employ nearly 200 people.
	Sector
	Business model The companies have been focusing on research, product launce, branding and expansion of market; however, the scope of products is still not wide.
	Turnover rate According to the Lithuanian Development Agency the annual turnover of the sector is expected to reach € 29-58 M. in 2006.
	Location
	Leaders / success stories
1.2. Research bases	Public / private expenditure
	 Main organisations Department of Biochemistry and Biophysics, Vilnius University Department of Chemistry and Bioengineering, Vilnius Gediminas Technical University Institute of Biotechnology (State Research Institute) Institute of Biochemistry (State Research Institute) Institute of Immunology, Vilnius University Kaunas University of Technology Kaunas Agricultural University
	Research fields of excellence - Agrobiotech - Bioanalysis - Biochemistry - Biomedics

that could offer specialized training for Lithuanian scientists.
Threats
- Lithuanian accession to the EU has increased costs of labour for the companies.

LUXEMBOURG Drafted by which partner?

	LUXEMBOURG
1. General overview	20122122 00110
1.1. Enterprises	Number of enterprises Very few life science companies are located so far in Luxembourg. Number of employees Sector Business model
	Turnover rate Location Leaders / success stories
1.2. Research bases	 Public / private expenditure About 1.7% of GDP are spent for R&D Main organisations - The University of Luxembourg is currently only offering bachelor degrees in life sciences - Several public research labs in Luxembourg belonging to the CRP Santé with several hundred employees. Research fields of excellence There are no research fields of excellence in Luxembourg worth of mention.
1.3. Financial environment	Types of funding 4 VC funds are located in Luxembourg, however only one is specialised in life science investments. There is one large incubator located in Luxembourg which is open for companies from the surrounding countries. Success stories Business Angels Access to business angel network
1.4. Supportive an policy environment	

	be located here.
	Programs
	Clusters
	Associations
2. SWOT Comments	Strengths
	- One of the largest financial sectors in Europe
	- A big advantage for Luxembourg is the short way between
	companies and policy makers.
	Weaknesses
	- Currently, Luxembourg is not a significant player in the Biotech segment.
	- There is no history in life science through an established
	university.
	Opportunities
	- Some potential due to the fact that the Government is supportive
	- The access to money may be easier than in other countries.

NORWAY

Drafted by ITD-Eu

	NORWAY
1. General overview	
1.1. Enterprises	Number of enterprises Total of 110 Norwegian companies utilising biotechnology as an important part of their business ⁴ . Small innovative start-ups represent the large majority. Almost half of the companies have been established since 1999 and more than 70% have less than 20 employees ⁵ . Many of these are materialising in close connection to the R&D institutions ⁶ and derive from academic spin-offs. There are relatively few multinational companies.
	Number of employees
	Sector 48 in biomedicine which is the dominating sector. Others are in agrofood, marine biotech, environment and bio processing.
	Business model
	Turnover rate Development and production of biotech and pharmaceuticals doubled their revenue from 1994 to 2003.
	Location Most of them are located around the two universities in the Oslo region. In 2003, 35% of the companies within the life science sector in Norway were located in Oslo, 61% of all employees within the biotech and pharmaceutical sector worked in an Oslo-based firm.
	Leaders / success stories The Norwegian biotech companies with the highest revenues in 2004 ⁷ : - Amersham Health (GE Healthcare) Turnover: 510M. € - BioMar A/S Turnover: 158 M. € - Nycomed Pharma Holding A/S Turnover: 134M. €

⁴ O.J. Marvik, 4bio AS on behalf of Innovation Norway, "Norwegian Life Sciences Overview and status", October 2005.

⁵ Ibid.

⁶ The main source of information regarding Norway comes from the Report "Life science in Oslo – a potential cluster?". Knut Halvorsen, Oslo Teknopol, study for STRATINC project (INTERREG IIIC), 2005.

cluster?", Knut Halvorsen, Oslo Teknopol, study for STRATINC project (INTERREG IIIC), 2005.

⁷ Both Norwegian-owned biotechnology companies and international companies with activities partly in the Norwegian biotechnology industry.

⁸ Ibid.

	New Norwegian-owned companies on the Oslo stock market in 2005 9:
	- DiaGenic
	- NorDiag
	- Biotec Pharmacon
1.2. Research bases	Public / private expenditure
	Main organisations
	 Three universities: the University of Oslo, the Norwegian School of Veterinary Science and the Norwegian University of Life Sciences where biomedicine is the stronger. State colleges and research institutes¹⁰ The Radium Cancer Hospital that has given rise to companies such as GemVax and PhotoCure
	 Stars Centre in Bergen that formed a partnership with the European Molecular Biology Laboratories (EMBL) in Heidelberg Technology transfer offices of the universities.
	The Oslo region concentrates 50% of the country's research effort. It is the leading Norwegian centre of research and industry within the biotechnology, medicine and health sector. Unique health registers and a positive attitude towards medical innovations places the Oslo region among the most outstanding test-markets in Europe ¹¹ .
	Research fields of excellence Norway has strong knowledge centres within several important areas including life science: biomedical, marine and agricultural biotechnology. The life science industry is at the forefront of a few specialised research areas: cancer, immunology and vascular diseases ¹² . Ownership of inventions has been transferred from the individual scientist to the academic institution.
1.3. Financial environment	Total equity investments
	Types of funding The selected science parks below invest their own risk capital at the very early stages of innovative start-up companies in the fields of life science and biotechnology: - Bioparken in Ås has its own investment company Biovekst AS and administrates public R&D funding as well to strengthen the transfer of technology and foster the formation and growth of business enterprises. - Tromsø Science Park: a seed capital fund is accessible to the Tromsø Science Park through NorInnova. - Oslo Innovation Centre: administrates public and private seed capital funds and invests own risk capital in selected projects. Other fund managers: BMI, Bioparken, Sarsia.

^{9 «} Major investments renew optimism", *Euro Biotech News*, N° 1-2, vol. 5, 2006.

10 http://www.forskningsradet.no/CSStorage/Flex_attachment/BiotekInEnglish.pdf

11 "Life science in Oslo – a potential cluster?", ?", Knut Halvorsen, Oslo Teknopol, study for STRATINC project (INTERREG IIIC), 2005. ¹² Ibid.

Professional players such as Medinnova, SINTEF/Unimed and the Research Foundation of the Norwegian Radium Hospital have evolved to assist the commercialisation of ideas within the life science sector.

Foreigners are well represented among the owners of biotech and pharmaceutical companies (40% of all the life science investments in the Oslo region)¹³.

Success stories

Business Angels

1.4. Supportive and policy environment

National / regional support

The present Norwegian government is promoting innovation from biotechnology and is focusing on eliminating bottlenecks. Life science and biotechnology are thematic priorities for the Research Council of Norway.

The total public investment in (experimental) life science through the Research Council amounts to approximately 830M. $\[\in \]^4$. In addition, through the Skatte FUNN scheme, the Government is providing tax incentives for R&D investments (In 2004: 512 biotechnological projects were concerned 15).

The investment made in the life science industry was 5 times larger in 2003 than in 1994, biotech and pharmaceuticals being by far the most growing sector¹⁶.

Programs

Two national programs:

- Functional genomics research (FUGE) has from 2001 contributed to building important technology platforms and to providing a good basis for biotechnological research. The plan will be continued, and further initiatives will be seen in connection with the plans for FUGE II for the period 2007-2011¹⁷.
- "Biobanks for Health": high-quality health registers, genealogical data and actual medical and genetic samples¹⁸.

Clusters

The three main clusters are located in the Oslo region:

- the biomedical cluster in the Gaustadbekk Valley,
- the veterinary medicine cluster at Adamstuen

¹³ "Life science in Oslo – a potential cluster?", ?", Knut Halvorsen, Oslo Teknopol, study for STRATINC project (INTERREG IIIC), 2005.

^{Ì4} Ibid

^{15 «} Major investments renew optimism", *Euro Biotech News*, N° 1-2, vol. 5, 2006.

¹⁶ « Major investments renew optimism", Euro Biotech News, N° 1-2, vol. 5, 2006.

White paper on research, Nowegian Ministry of research and Education, Report 2004-2005 http://odin.dep.no/filarkiv/271190/FM05English.pdf

¹⁸ « Major investments renew optimism", Euro Biotech News, N° 1-2, vol. 5, 2006.

- the biological research cluster at Ås.

Associations

Networks within the life science sector in Oslo:

- MedCoast Scandinavia (Norwegian-Swedish cooperation) aims to establish one of the leading bioregions in Europe where world-class researchers, a well-developed health service and excellent working conditions form an attractive environment for investors within the biotech and healthcare sector
- The Norwegian Bioindustry Association promotes the development of Norwegian biotech trade and research. It is a member of EuropaBio.
- In addition, Oslo Teknopol is the leading partner of the Connect Baltic Sea Region (CBSR), a three-year project co-financed by the INTERREG III B Programme which objective is to stimulate new firms and job creation in the knowledge-intensive sector, by linking entrepreneurs and innovators with R&D, service providers, venture capitalists and partners. CBSR aims to establish Connect networks throughout the Baltic Sea Region
- NorBioBase: database maintained on a permanent basis as a primary industry information resource for biotechnology.

2. SWOT Comments

Strengths

- Relatively high degree of collaboration among entrepreneurs and between them and regional policy makers¹⁹.
- Robust basic research communities

Weaknesses

- Limited availability of seed and venture capital, few biotech venture companies and limited experience in biotech commercialisation²⁰.
- Lack of political focus on dedicated innovation strategies.
- Lack of strategic information and cross-border collaboration in SMEs.
- Lack of experience management.
- Lack of direct inventions or experiences from other companies for start-ups. As a consequence, Norwegian companies tend to grow more slower than their international competitors.
- Lack of available in-house competence and resources for SMEs make it very difficult to approach and work within the European environment of legislation and regulation.
- Lack of communication between R&D and business communities²¹.

Opportunities

- Great potential for increased innovation.
- Enterprises have a strong need for research-based knowledge.
- Biotechnological research and industrial development have a great future potential.
- Norway's close proximity to the rest of Europe opens the possibility

1.

¹⁹ ibid

 $^{^{20} \, \}underline{\text{http://www.forskningsradet.no/CSStorage/Flex}} \, \, \underline{\text{attachment/BiotekInEnglish.pdf}} \,$

²¹ "Life science in Oslo – a potential cluster?", ?", Knut Halvorsen, Oslo Teknopol, study for STRATINC project (INTERREG IIIC), 2005.

- for extensive cooperation with other Nordic countries, the rapidly growing markets of Eastern Europe and the countries of the EU.
- Blue biotechnology (marine)
- Difficulties to raise VC money but renewed optimism during the past few years and several listings on the stock market.

Threats

- Oslo Teknopol: the life science cluster is small and the amount of new investment projects is not yet at a comparable international level.
- A majority of small companies depend on consultants and service providers.
- Risk that the enterprises technological opportunity window closes before they are ready to market their products.

PORTUGAL

Drafted by Milano San Raffaele Science Park

	PORTUGAL
1. General overview	
1.1. Enterprises	Number of enterprises Around 40, but only 17 are completely dedicated to biotechnology, while the remaining are companies of services related to the biotech industry.
	Number of employees Around 1500.
	Sector Almost all the companies are involved in human healthcare.
	Business model
	Turnover rate Since biotechnology is relatively new in Portugal, there are no official economic data about the sector yet.
	Location All of the biotech companies are located in the Lisbon area.
	Leaders / success stories
1.2. Research bases	Public / private expenditure The Government is committed to increase the expenditure in R&D. The total budget for 2000 amounted to almost €500 M Although funds for research and technology are increasing, many of those resources are not devoted to the life science sector.
	 Main organisations Toguspark (Lisbon) Abel Salazar Biomedics Institute (Porto) Instituto de Tecnologia Quimica e Biologica (Oeiras) Instituto de Biologia Experimental e Tecnologica (Oeiras) Instituto Gulbenkian de Cienca (Oeiras)
	Research fields of excellence There are no research fields of excellence in Portugal worth mentioning.
1.3. Financial environment	Total equity investments No figures available about annual equity investments in biotech.
	Types of funding Investments in biotech companies are still too few to support the sector, and come from the public sector. There is lack of VC industry, although in1999 approximately €200 M. was available from VC's to invest in new technology.

	Success stories
	Business Angels
	Business Angels are not organized, maybe not even existent.
1.4. Supportive and	National / regional support
policy environment	In 2000-2006, the Government started an EU funded program to provide a
	financial support for industrial development, called PEDIP II. This program
	allocated €320 M. in different projects aimed to support strategic
	development of science and technology institutions (€100 M.), industrial
	R&D projects (€70 M.), entrepreneurship (€150 M.), and academia-industry
	partnerships (€20 M.).
	Programs
	Clusters
	The only biotech cluster in Portugal is located in Lisbon.
	Associations
	The Portuguese Association of Bioenterprises is at www.apbio.pt (the
	website is under construction, something to blame since the association was
	constituted in 1997).
2. SWOT Comments	

	SPAIN
1. General overview	
1.1. Enterprises	Number of enterprises Around 300, but only 24% (71) are completely dedicated to biotechnology, and the remaining are partially involved in biotech or/and are companies of service related to biotech industry.
	Number of employees The number of employees is around 1700 in the 71 main biotech companies, while the total number of employees is around 18487.
	Sector
	Business model Twenty-four percent of the companies have a strong R&D, product – or medical devices-oriented business model, 26% of the enterprises have a mixed business model (partially R&D oriented and partially service oriented), while the remaining 50% has a service business model.
	Turnover rate It is difficult to get data about the biotech sector only in Spain. The official data regards total turn-over of the biomedical industry, which was €2.7bn (1998).
	Location More than 50% of the biotech companies are located in the Barcelona and Madrid areas.
	Leaders / success stories
1.2. Research bases	Public / private expenditure The National Plan for Scientific Research, Development and Technological Innovation (PN I+D+I 2004-2007), which complements the EU Framework program (available on the website for the Ministry for Science and Education, www.mec.es), The National Plan for R&D and Innovation for 2004-2007 is targeting for R&D spending to reach 1.4% of GDP in 2007 (in 2003 spending stood at 1.1% of GDP, up 14.2% from 2002, with 29% of the funds channelled into R&D services and 10% into pharmaceutical products).
	Main organisations - Barcelona Science Park (Barcelona) - Spanish National Genotyping Center (Barcelona) - Spanish National Cancer Centre (Madrid) - Carlos III Health Institute (Madrid) - Cajal Institute (Madrid)

	- Madrid Scientific Park (Madrid)
	The second of the (Madile)
	Research fields of excellence
	- Agrobiotech
	- Environmental Biotech (biofuels)
	Neurodegenerative DiseasesOncology
	- In-vitro fertilization
	- Biobanks
1.3. Financial	Total equity investments
environment	No figures available on annual equity investments in biotech, although in 2003 VCs invested €5 M. in biotech companies.
	Types of funding
	Investments into the biotech companies are still too few to support the sector. Moreover, the only funds available are public and personal ones, enough to start a company but not to sustain it.
	Success stories
	Business Angels Business Angels are not organized.
1.4. Supportive and	National / regional support
policy environment	The National Plan for Scientific Research, Development and Technological Innovation (PN I+D+I 2004-2007) focuses on the participation of private enterprise, increasing the number of researchers and reinforcing coordination and cooperation at all levels. The National Plan also contains specific measures to support companies and other entities, which are regulated by the <u>Program for the Promotion of Technical Research</u> (PROFIT).
	Programs
	PROFIT provides incentives to companies which apply new findings in the field of productive processes and which carry out R&D activities. Finally, there is also special support for business start-ups: the NEOTEC initiative, which works with innovating companies beginning operations (See Centre for Technological Development).
	Clusters
	The two biotech clusters in Spain are located around Barcelona and Madrid.
	Associations The Spanish Association of Bioenterprises is at www.asebio.com
2. SWOT Comments	The Spanish Table and of Brochespines is at www.mascoloreom

AFIBIO – Access to Finance in the Biotech Sector Priority 2004-FP6-INNOV-6 Research and Innovation Contract number n°022560 WP1 - Deliverable 1.1. Overview of the Biotech-Health Sector in Europe

SWEDEN

Drafted by the Institute of Baltic Studies

	SWEDEN
1. General Overview	
1.1. Enterprises	Number of enterprises Estimated around 230. 60% of biotech companies are very small, employing up to 10 workers.
	Number of employees Some 33% of companies employ 10-100 people and only 7% of companies employ more than a 100 workers. The number of employed people in biotech and pharmaceutical industries is estimated to be between 30 000– 40 000.
	Sector A majority of the companies work in the area of pharmaceuticals and medicine. Approximately 20% are concentrated in biotech tools and supplies; other areas include bioproduction, agrobiotechnology, functional food and feed, environmental biotechnology.
	Business model
	Turnover rate Biotech has grown more rapidly than any other main Swedish industry in the past few years with an annual growth rate of 10 % between 1995 and 2003.
	Location
	Leaders / success stories

1.2. Research bases

Public / private expenditure

Main organisations

- Chalmers University of Technology
- Gotland University College
- Göteborg University
- Halmstad University College
- Karlstad University
- Karolinska Institute Stockholm
- Linköping University
- Lund University
- Mid-Sweden University College
- Mälardalen University
- Royal Institute of Technology
- School of Bioenergy, Växjö University
- Stockholm School of Economics
- Stockholm University
- Swedish University of Agricultural Sciences
- Swegene
- Umea University
- University College of Kristianstad
- University College of Skövde
- University College of Trollhättan/Uddevalla
- Uppsala University
- Örebro University

Research fields of excellence

- applied microbiology
- biochemistry
- bioimaging
- bioinformatics
- biophysical chemistry
- biophysics
- biomedical engineering
- biomedical nutrition
- bioprocess technology
- cell biology
- environmental microbiology
- genomic
- materials chemistry
- microarray
- molecular biology
- molecular biotechnology
- molecular medicine
- polygenic diseases
- protein chips
- proteonomics
- tumor biology

	The most important sectors of R&D today include drug discovery in metabolic diseases, immunology and neuroscience as well as advanced
	tools for diagnostics and bio production.
1.3. Financial environment	Total equity investments The Swedish pharmaceutical industry annually spends around 25% of its revenues on R&D.
	Types of funding The main sources of public start-up funding in Sweden are NUTEK, the Swedish Business Development and VINNOVA, the Swedish Agency for Innovation Systems. Another major player is Almi providing services, funding, patenting and advice on a local level. The Regional Councils locally cooperates with the abovementioned actors, supporting with seed-capital and interacting financially with bodies like Teknikbrostiftelserna, Swedepark, The Swedish Science and Technology Park and Swedspin, The Association of Swedish incubators.
	Success stories
	Business Angels
1.4. Supportive and policy environment	National / regional support The collaboration between academia, industry and public healthcare is extensive and gives an extra boost to pioneering companies in biotech.
	Programs
	Clusters There are three major biotech clusters in Sweden, the Stockholm-Uppsala Bioregion being the largest, followed by Medicon Valley around Malmö-Lund and Medcoast by Gothenburg. Other centers with advanced biotechnology research and high quality companies include Linköping and Umeå.
	Associations
2. SWOT Comments	 Strengths Sweden has a long pharmaceutical tradition, paired with an established financial and VC market, collaborations, major spin-outs and world class science. Highest number of biotech companies per capita in the world. In Europe Sweden ranks fourth and globally ninth in the biotechnology sector. Even though most of the businesses are rather small, there is a spirit of collaboration in Sweden that benefits these young firms and their partners. Sweden is home to the fastest growing venture capital markets in the world, much of which has been dedicated to the life sciences industry. Sweden tops the list of industrialized countries in terms of investing the greatest proportion of their gross domestic product in 'knowledge',

- defined as education, software and research spending.
- Sweden also has one of the most research friendly stem cell research legislations in the world.
- Swedish publications in clinical medicine are also the worlds most-cited, in relation to the population.

Weaknesses

- In most cases, the research findings of biotech companies are being commercialised outside Sweden.

Opportunities

- Sweden can offer an internationally competitive environment for drug development.
- Sweden has various advantages as a setting for the modern genomicsbased drug development work that is evolving from the mapping of genomes.

Threats

- The challenge ahead will be to capture the full potential of Sweden's technical knowledge and combine it to take Swedish biotech to the next level in an increasingly competitive international environment.
- Today a number of countries have caught up with Sweden both in terms of the quality of medical care and investments in medical research.

UNITED KINGDOM

Drafted by Cardiff University

	UK
1. General overview	
1.1. Enterprises	Number of enterprises 455 bioscience companies
	Number of employees 22 404 people and R&D employment of 9644 people.
	Sector
	Business model
	Turnover rate Total Biotech market value was about €11bn and sales value was about € 2.3 bn in UK (Source: Financial Times 19.052004). The revenue was € 5041M. in 2003.
	Location Cambridge is Europe's strongest bioregion in terms of research excellence and globally significant, it has many Nobel Prize winners. Major pharmaceutical research sites are located close by. Very good biotechnological supporters. 150 specialist biotechnology companies and 200 supporters Oxford is slightly less globally accomplished, but internationally significant. 50 specialist biotechnology companies and 200 supporters Cardiff is modestly significant, nationally and some internationally. 10 specialist biotechnology companies and 50 companies relating to biotechnology.
	 Leaders / success stories Cambridge Antibody Technology (CAT is a biopharmaceutical company committed to develop human monoclonal antibody therapeutics) (Product). Oxford Glycoscience (was acquired by Celltech, which was acquired by UCB) (Product) Cardiff: Molecular Light Technology Research Ltd (medical devices/technologies)
1.2. Research bases	Public / private expenditure Total R&D expenditures dedicated to Biotech in UK was € 1757 M. in 2003
	Main organisations - Cambridge University: Babraham Institute, Laboratory of Molecular biology, The Sanger institute, The European

Bioinformatics Institute(Cambridge),

- Oxford University: Edward Jenner Institute for Vaccine Research, AEA Technology, MRC Radiobiology Institute, Welcome Trust Human Genetics Centre,
- Cardiff University: UWCM, Centre for Mammalian Post-Genomic Research (Cardiff), Cardiff Medicenter

Hospitals or university hospitals:

- Cambridge: Addenbrooke's Hospital
- Oxford: John Radcliffe Hospital
- Cardiff: University Medical School

Research fields of excellence

Cambridge: genomics and post-genomics related i.e. Sanger Institute, MRC, CAT

Oxford: Bioinformatics related, i.e. Oxford Glycoscience, Oxford Molecular, Oxford Asymetry

Cardiff: Genomics/oncology research i.e. Nycomed Amersham

1.3. Financial environment

Total equity investments

Capital market has slowed down since 2001 in UK. Total biotech market value was about 11bn € and sales value was about 2.3bn € in UK (Source: Financial Times 19.05.2004).

Total Equity investments in Biotech were €554 M., Venture Capital was € 247m, Private placements were € 160 m and Pulic Equity Offering was € 91m in 2003.

Investments in the cluster 2002/2003/2004/2005 compared to overall life science investments with private equity:

Cambridge and Oxford: approx. 100 M. €

Cardiff: approx. 25 M. €.

Types of funding

- Existence of VC/Seed funds dedicated to the Biotech sector
 - Merge and consolidation,
 - Initiated in the UK and then move to US for development and commercialisation. New VC strategy of "conveyor belt" or "decapitation".

Some limited VC investment, i.e. Ark, some direct licensing by pharma, 'decapitation', intermediaries. 2005 Ark Therapeutics Ltd is good at AIM with 80.74M. € in 2004 as the third of top 10 global Biotech IPOs.

Drain to US stock exchange: decapitation, Pharma HQ (de facto Glaxo), acquisitions.

- Types of funding (seed, development, exit)
 - Small firms bought by larger companies, often US
 - Two small firms merged together
 - Larger DBF was even acquired by other big companies
 - For example:

- o RiboTargets was taken over by British Biotech, which was in 2003 acquired by OSI (US) and Vernalis of the UK.
- o Oxford Glycosciences by Celltech, which was acquired by UCB in May 2004 with the deal value of £1,530m.

Success stories

Types of companies funded (products, services, mixed, medical technologies):

- Cambridge: CARTESIA
- Oxford investment Opportunity Network (OION)
- Cardiff: XENOS

Business Angels

British Business Angels association is organised (EBAN)

1.4. Supportive and policy environment

National / regional support

Non-firm organisation, including network or partnership organisation play an important role for sustaining the biotechnology. The UK biotech support sector has grown rapidly to more than Biotech, demonstrating the importance of biotech clusters on economic growth.

The UK sector has grown rapidly to more than biotech, demonstrating the importance of biotech clusters on economic growth. Non-firm organisations, including network or partnership organisations play an important role for sustaining biotech.

Programs

Clusters

- Cambridge cluster
- Oxford cluster
- Guildford-London bioregion
- Scotland-Edinburgh cluster
- Wales bioregion

Associations

2. SWOT Comments

Strengths

- UK leads Europe in biotechnology. Cambridge is Europe's strongest bioregion in terms of research excellence.
- Biotechnology sales by UK industry is about 9bn pounds, holds most promise account for almost a quarter of all UK's industrial output, employment and export earning, including pharmaceutical, agricultural and food.
- Factors for success: strong science base; effective networks between universities, hospitals, suppliers, advisers and financiers; ability to attract key staff; entrepreneurial culture,

availability of finance, excellent R&D, supportive policy environment; attractive business environment

- TT remains good

Weaknesses

- Commercialisation is difficult
- The early stage financing is limited and is a key constraint for technology transfer and exploration in market is slow. New structure strategy to accelerate the commercialisation is needed.
- In recent years, the venture capital community has invested in fewer companies, although those that do receive finance do get larger amounts than previously.
- A growing trend for venture capitalists to provide more support for either the most promising of their portfolio companies or in companies that are believed to have the potential for being asset consolidators.
- The big companies focus more on development than discovery.

Threats

- The big companies focus more on development than discovery

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ANNEX 1 – ADDITIONAL DEFINITIONS OF THE BIOTECH SECTOR

1) OECD definition

http://www.oecd.org/about/0,2337,en_2649_37437_1_1_1_37437,00.html http://www.oecd.org/document/41/0,2340,fr_2649_37437_1933994_1_1_1_37437,00.html

Biotechnology has been defined as "the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services". In recent years, biotechnology has had an increasingly important impact on a range of economic sectors and disciplines. With such a growth, the need for effective policies has become a national and international priority.

The single definition

The provisional single definition of biotechnology is deliberately broad. It covers all modern biotechnology but also many traditional or borderline activities. For this reason, the single definition should <u>always</u> be accompanied by the list-based definition which operationalises the definition for measurement purposes. The single definition is:

The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.

The list-based definition

The following list of biotechnology techniques functions as an interpretative guideline to the single definition. The list is indicative rather than exhaustive and is expected to change over time as data collection and biotechnology activities evolve.

The list-based definition of biotechnology techniques:

DNA/RNA: Genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling, and use of antisense technology.

Proteins and other molecules: Sequencing/synthesis/engineering of proteins and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein isolation and purification, signaling, identification of cell receptors.

Cell and tissue culture and engineering: Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation.

Process biotechnology techniques: Fermentation using bioreactors, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation, biofiltration and phytoremediation.

Gene and RNA vectors: Gene therapy, viral vectors.

Bioinformatics: Construction of databases on genomes, protein sequences; modelling complex biological processes, including systems biology.

Nanobiotechnology: Applies the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics etc.

2) Europabio – the same as OECD

http://www.europabio.org/bi glossary.htm#B

Biotechnology: the application of biological research techniques to the development of products which improve human health, animal health, and agriculture.

3) Critical I Limited for the purpose of its study (Comparitive Study 2005)

"In this survery we include only companies whose <u>primary</u> commercial activity depends on the application of biological organisms, systems or processes, or on the provision of specialist services to facilitate the understanding thereof are included in the remit of this study.

Big pharma companies, other major corporates, and companies for whom biotechnology is an important but, nonetheless, minor part of their business are not included in this study. Dedicated biotechnology subsidiaries of major corporates are included, however. As a result, the study does not, and was not designed to reflect, the full scope and extent of biotechnology activity in the countries surveyed. This is particularly relevant in the Agricultural and Environmental sectors where the number of pure play biotechnology companies is extremely limited, albeit that biotechnology-based techniques are both a widespread and increasingly vital part of their technology mix.

A rigorous application of this definition, likewise, means that many companies who might, and indeed, often do feature in reviews of the biotechnology industry have been excluded from this study. Examples include companies such as R&D Systems, Genetix, Applied Biosystems and Quest Diagnostics, to name a few. By the same token, companies such as Novo Nordisk and Serono have been included, not withstanding their scale, because they do satisfy the definition above".