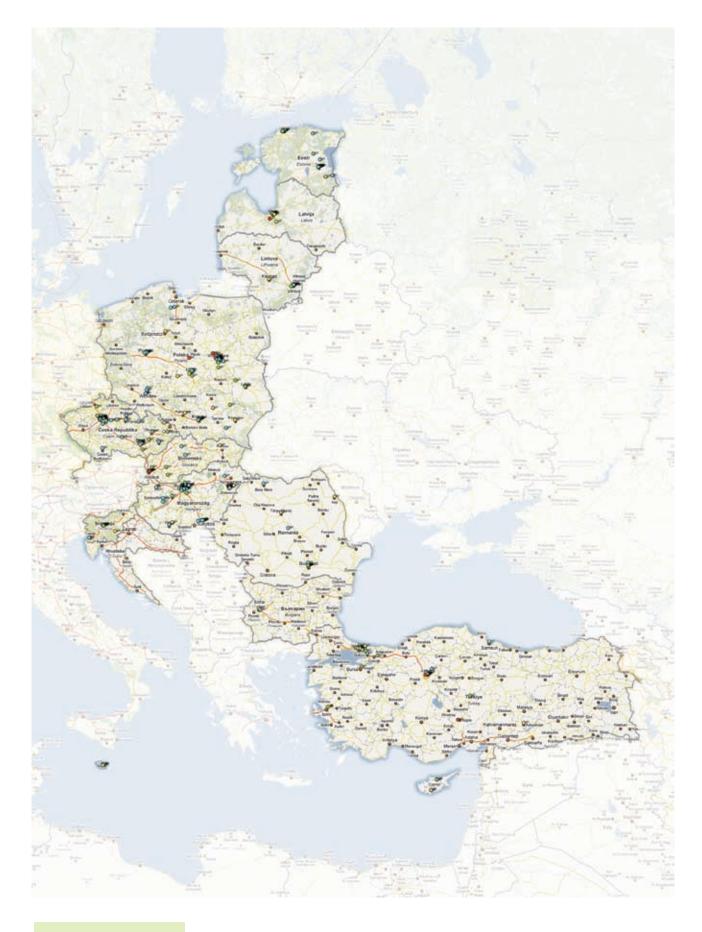


Biotechnology Report

BIOTECH IN THE NEW EU MEMBER STATES:

AN EMERGING SECTOR

PREPARED BY EUROPABIO AND VENTURE VALUATION IN 2009



- Biotech-Therapeutic
- Biotech-Other
- Biotech-Services
 - Pharmaceutical

FOREWORD

This report is the first of its kind to try and understand the state of the biotechnology industry in the new Member States and candidate countries. As with any bottom-up work, it took a lot of effort and persistence to gather data on current and prospective developments in this area. Our goal was to strengthen the understanding of the European biotechnology scene and we believe that with the knowledge accumulated we have reached this goal. This report should enable policy makers and investors to make informed decisions about biotechnology support and development. The databases developed during this project will also provide better international visibility to the companies, which could lead to new cooperation or investment.

Knowing the strengths and weaknesses of each country facilitates the implementation of appropriate measures to help countries face their particular challenges, cultivate their core competencies and take advantage of their opportunities. Following this report and its presentation at different events, general and country specific recommendations have been formulated. These recommendations can facilitate the development of a positive policy environment for this promising industry.

The biotechnology sector in the new Member States and candidate countries is still young and immature and the status of development in the region is very uneven with four countries standing out by the size of their biotechnology sector. Hungary, the Czech Republic, Poland and Estonia have mostly been the early movers in the biotechnology sector, or the ones with a coherent framework for biotechnology and innovation.

Outsourcing research or manufacturing in the new Members States and candidate countries is a growing market for the biotechnology sector and an opportunity for those countries to develop stable know-how and wealth in the healthcare sector before moving into more advanced R&D and drug development. Outsourcing can be used as a stepping stone but is unlikely to be a sustainable growth sector due to the fierce competition with China and India.

There is a need for a critical mass of innovation, support, resources in terms of manpower and financial means to allow companies to flourish. Thus the countries that are successful and will be successful in the long-term are the ones putting in place a coherent (taking into account the multiple aspects of innovation support) and consistent (long-term) framework with support dedicated to the biotechnology and healthcare sector.



Mr. Willy De Greef Secretary General EuropaBio Brussels, Belgium



Dr. Patrik Frei CEO Venture Valuation AG

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EXECUTIVE SUMMARY

Until now, biotechnology data gathering initiatives in Europe have tended to focus on the most developed biotechnology industries, with limited attention given to life science companies in the 12 new Member States and 2 candidate countries. The 14allbio (InDeCS-H) report aims to fill that information gap.

Tools to Asses Biotechnology Development

The goal of this report was to measure the development of biotechnology in the new Member States and candidate countries. This was achieved through establishment and calculation of a Development Capacity Index (DCI). The Index uses both quantitative factors, such as the number of biotechnology companies present and the number of products in the pipeline, and qualitative parameters, such as the level of government support and infrastructure development. Along with calculation of the DCI, reports containing a more thorough analysis were produced for all countries, highlighting the strengths and weaknesses of the industry. The national reports focus on the wide range of economic situations, industry infrastructures, regulatory frameworks, and government involvement in R&D and biotechnology.

Policy Recommendations Document

For the purpose of policy recommendation at the national and EU level, countries were divided into four groups based on the level of development determined from the collected data. Focus points included the existing skill and knowledge base, presence of support structures for biotechnology and SMEs, available funding opportunities as well as intellectual property and technology transfer development. Recommendations were discussed and reviewed during the workshops that took place in Budapest, Vilnius, Prague and Brussels in September 2009 and a separate document was issued.

State of the Biotechnology Industry in the 14 New Member States and Candidate Countries

This study identified 260 biotechnology companies currently operating in the 14 new Member States and candidate countries. The biotechnology sector in these 14 countries is smaller and less developed than that of their Western European neighbours; however, some countries such as Hungary, Poland and the Czech Republic, followed closely by Estonia, are leading the group and are already on par with some Western European countries. These 4 countries report the highest numbers of biotechnology companies and the most developed biotechnology sectors among the 14 countries analysed.

Key Features

A moderately developed biotechnology sector, with well balanced support structures and political programmes for SMEs and biotechnology, already exists in several countries with a relatively high number of active companies. The development of R&D and the biotechnology sector has been declared as a national priority by most of the countries but this has not always been put into practice. The financial crisis, among other reasons, has resulted in a shift of political focus away from biotechnology. There is an overall lack of awareness and information on available resources both at EU and national levels, and in some cases funding opportunities are rather scarce. Although there is a strong research base, the majority of R&D is conducted at universities and institutes and collaboration with industry is often rather limited. One of the main challenges for the biotechnology sector is to turn innovation into products

as the environment for product commercialization is not always favourable. Awareness of, and interest in, IP protection rights and the patenting process is often low and education and effective technology transfer offices are needed to stimulate commercialization of ideas.

Around 70% of the biotech companies in the 14 Member States and candidate countries operate as services firms with a large portion performing contract research and manufacturing. Whilst product development achievements are currently not very visible, many of the countries are at various phases of establishing the framework and infrastructure necessary for the future successful development of the biotechnology sector.

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INTRODUCTION

The 14allbio (project acronym InDeCS-H) project was funded by the European Commission's 6th Framework Programme and designed to gather, analyze and distribute data about the biotechnology industry in Bulgaria, Croatia, Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, the Slovak Republic, Slovenia, and Turkey¹.

Historically there has been a lack of comparative data about life sciences companies in Europe. Recent data gathering initiatives have focused on more developed biotechnology sectors with little focus on life science companies in the 14 new Member States and candidate countries. A comparative study titled "Biotechnology in Europe: 2006" was completed by Critical I and EuropaBio as an effort to increase the transparency of the sector. As the biotechnology industry in these 14 countries is still largely in the early stages of development, and in many cases going through major reorganisation after transition from a planned economy to market economy, complete and comprehensive information is difficult to gather. The fact that the industry is spread out across different sectors, regions, and disciplines also makes obtaining an overview of the sector challenging.

This project was initiated with the goal of building a data collection system for the biotechnology sector in the 14 new Member States and candidate countries which is comparable country to country and can be benchmarked against existing data from Europe. This data can then be used for statistical analysis, to identify gaps and to analyse trends for the purpose of policy recommendation aimed at supporting the development of biotechnology in these countries.

As part of the project, comprehensive online databases have been created for each country to gather company data with the help of local partners and the companies themselves (see appendix B). This report was compiled to present key data obtained from the databases and through interviews with local and international partners as well as companies operating in the region.

The company databases as well as this report have been made publicly available with the intent of increasing the visibility of the sector as well as facilitating business development and partnering among individual companies, institutions, investors and venture funds. This will increase awareness among the media, regional, national, and European authorities, as well as among international companies and investors.

1 Collectively referred to as the 14 new EU Member States and candidate countries throughout this report.

The 14allbio project was carried out by the following partners:

EuropaBio



EuropaBio, the European Association for Bioindustries, was created in 1996 to provide a voice for the biotechnology industry at the EU level. The association's mission is to promote an innovative and dynamic biotechnology-based industry in Europe. It has 72 corporate and 6 associate members operating worldwide, 4 Bioregions as well as 25 national biotechnology associations representing some 1800 small and medium sized enterprises.

Venture Valuation AG

VENTURE VALUATION

Venture Valuation specializes in independent assessment and valuation of companies in high-growth markets, such as biotechnology and medical technology. Furthermore, the company also provides information services such as the global Biotechnology Database (www.biotechgate.com) and over 25 country databases for clients around the world such as Bio Alberta, BioAlps, BioCom San Diego, BIOTECanada, Biovalley, ChinaBio, Maryland, Medicon Valley, the Swiss Stock Exchange, Swiss Biotech and many others.

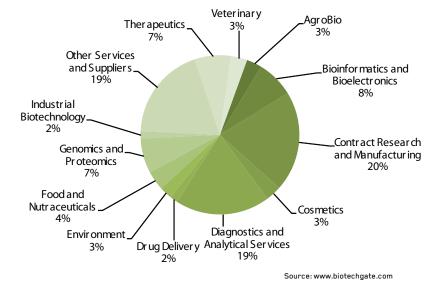
STATUS OF THE SECTOR 2008

(Financial data in €)		
260	Total Biotech Companies	
29	Biotech-Therapeutic	
177	Biotech-Services	
54	Biotech-Other	
>10'000	Employees	
>1'900	R&D employees	
>19 m	R&D spending*	
>345 m	Revenue*	
8.6 m	Equity Raised*	
0.025 m	Government grants*	
89%	Percentage of SMEs	
2%	Percentage of companies publicly owned	

* As some private companies do not disclose financial figures the above is based on available information only.

Size of the Biotechnology Sector

This study identified 260 biotechnology companies operating in the 14 new Member States and candidate countries. 29 of these companies report research and development of human therapeutic compounds as their main activity, 55 operate in other biotechnology areas such as veterinary therapeutics, agribio and industrial biotechnology, and the overwhelming majority of 176 companies operate by providing biotechnology services such as contract research (CRO), diagnostics, manufacturing, and analytical services among others.



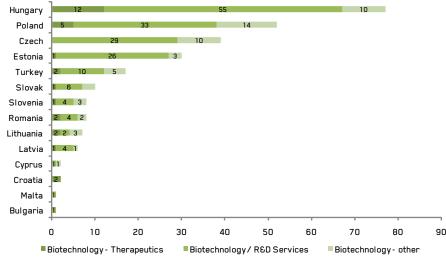
Biotechnology Companies in the 14 New Member States and Candidate Countries Breakdown by Subcategory based on 383 entries by 260 companies

These numbers reflect a small and recent biotechnology sector in this region when compared to Western countries such as Germany and Switzerland, which together house over 1000 biotechnology companies, with nearly 200 of them developing human therapeutics. This disparity is natural as many of the new Member States have recently undergone drastic overhauls of government and economic policies and have only recently establish development strategies and funding for the biotechnology sector. Most of the 14 new Member and candidate states have identified the development of a high tech and/or biotechnology sector as an economic development opportunity and expressed (to various

degrees) interest in its nurturing. Despite the small size of the sector (when compared to best European performers), there are many opportunities for growth in this area with appropriate support and funding.

Hungary, Poland and the Czech Republic, followed closely by Estonia, report the highest numbers of biotechnology companies and the most developed biotechnology sectors among the 14 new Member States and candidate countries. Many of the other countries in the region are at the early stages of establishing a favourable environment for the industry and therefore report fewer operating companies.

Key Activities of Biotechnology Companies



Biotechnology Companies in the 14 New Member States and Candidate Countries

Source: www.biotechgate.com

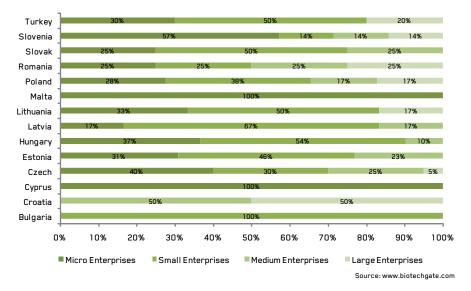
"Almost 70% of the biotechnology companies in the 14 new Member States and candidate countries operate as services firms with a large portion performing contract research and manufacturing" Almost 70% of the biotechnology companies in the 14 new Member States and candidate countries operate as services firms with a large portion performing contract research and manufacturing. This is not significantly different from the situation in Germany and Switzerland where roughly 2/3 of biotechnology companies are focused on services. Service companies operating in the new Member States and candidate countries may have certain advantages over their Western competitors: wages in these countries are traditionally lower and the region is establishing itself as a 'technology outsourcing' destination. In a time when research and development funding is scarce, particularly during later stages of product development, the services sector is also an attractive means of generating liquidity to fund other R&D projects such as therapeutics development .

In the development of a healthy biotechnology sector, the presence of therapeutics companies tends to reflect a higher degree of advancement. Therefore, creating an environment that promotes the establishment and perpetuation of these companies is often described as the ultimate goal of biotechnology development, as these companies engage in the most lucrative activities which attract foreign investors. However, it is important to underline that therapeutic development may not be the highest wealth and employment generator for a country. The development of a biotechnology service sector; with focus on drug manufacturing, generic and active pharmaceutical ingredient production, diagnostics development or clinical trial structures; contributes to the creation of scientific and managerial know-how in the health sector and results in the creation of employment and new economic opportunities. It also

promotes the establishment of R&D and SME support infrastructures which benefit more advanced R&D development. Many countries with an emerging biotechnology industry, such as Israel, China and India, first promoted a strong biotechnology services industry where the 'copying' and manufacturing of healthcare biotechnology products was encouraged prior to moving into therapeutics development.

Size of Biotechnology Companies

The vast majority of biotechnology companies operating in the 14 new Member SMEs in the 14 New Member States and Candidate Countries

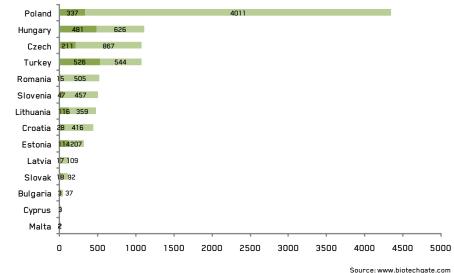


States and candidate countries are small and medium-sized enterprises (SMEs) employing less than 250 people². Over a third further qualify as micro enterprises employing less than 10 people and almost half are small enterprises with 11 to 50 employees. This distribution is also consistent with the situation in Western countries such as Germany and Switzerland.

² The EU definition of an SME is a company employing less than 250 people with revenues of less than EUR 50 million and a balance sheet total not exceeding EUR 43 million. As financial data was largely undisclosed by the companies surveyed in this paper, the number of employees was the only criteria used in determining company classification as a micro, small or medium enterprise. [Microenterprise: <10 employees; small enterprise: 11-50 employees; medium enterprise: 51-250 employees; large enterprise >250 employees]

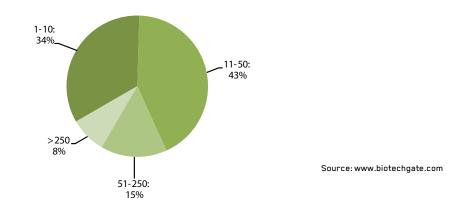
Employment in Biotechnology Companies

 $\label{eq:people Employed in Biotechnology in the 14 \ \mbox{New Member States and Candidate Countries}$



The biotechnology sector employs over 10'000 people in the new Member and accession states with almost 2'000 dedicated to R&D. Poland reports the highest numbers of biotechnology workers, which is mainly due to 5 large enterprises operating in the country, one of which employs over 1'500 people in synthesis services. Hungary, the Czech Republic and Turkey each employ around 1'000 people in the industry, while Romania, Slovenia, Lithuania and Croatia hover around the 500 people mark and smaller countries such as Cyprus and Malta report lower numbers.

Biotechnology Company Size in the 14 New Member States and Candidate Countries (number of employees)

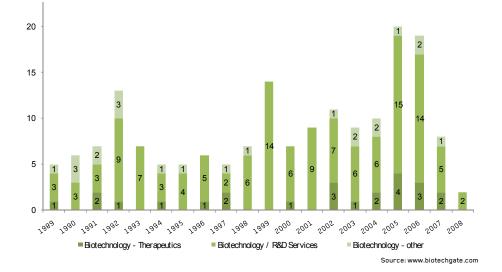


Company Foundation Timeline

Over the past 20 years the foundation of new biotechnology companies in the 14 new Member States and candidate countries has been rather steady with a spike in 2005 and 2006. In 2008, however, as the financial crisis reached its peak, only two company foundations were identified in the region. The majority of companies were founded independently and nearly 15% were founded as spin-offs from universities or institutes.

Number of R&D Employees

Number of non R&D Employees



Company Foundations in the 14 New Member States and Candidate Countries

INDUSTRY OVERVIEW

In most cases, the biotechnology sector in the 14 new EU Member States and candidate countries is smaller and less developed that in their Western European neighbours. Political instability, underdeveloped infrastructures, limited access to funding and in many cases, the relatively recent transition from a planned to a market economy all contribute to this disparity.

Nonetheless, most of the 14 new EU Member States and candidate countries have identified the development and support of a biotechnology and healthcare sector as a priority in their economic plans. The extent to which this declaration is supported by funding and concrete programmes differs from country to country, with some countries such as Hungary targeting specific areas of development and others such as Malta taking a more opportunistic approach and focusing on attracting foreign investment.

Ten of the 14 new EU Member andcandidate countries, with the exception of Bulgaria, Cyprus, Maltaand Slovenia, have established biotechnology associations that promote their companies and facilitate networking both domestically and abroad. Some, such as the Romanian Association of Biotechnology, are acting mainly as a networking platform for academics while others, such as the Hungarian Biotechnology Association, are quite assertive in promoting their companies at international conferences. The presence and development of such organisations shows the necessity to introduce structure as a sector grows in order to increase visibility, create cooperation opportunities, have representation for the industry and generate interest among investors.

As the surveyed countries are at different stages of development and have unique specialisations and advantages in various areas of biotechnology, each of them is facing a distinctive set of challenges and opportunities in their path forward. Some countries, such as Latvia and Hungary, have a strong pharmaceutical manufacturing history to build on while others, such as Turkey and the Czech Republic, have a strong base in the agri-food sector and industrial biotechnology sectors respectively. As a result, the greatest benefit can be achieved by tailoring future programmes to the unique strengths and weaknesses of each country. "Most of the 14 new EU Member and accession states have established biotechnology associations that promote their companies and facilitate networking both domestically and abroad" "Higher GDP does not mean a more successful biotechnology sector"

Political and Economic Environment

The majority of the 14 countries covered by this report joined the European Union in 2004, with Bulgaria and Romania joining in 2007 and Croatia and Turkey currently candidates for membership. Although the political environment of all the surveyed countries can be considered as relatively stable, many of the countries have undergone significant political, structural and ideological changes over the past few decades. 11 of the 14 new EU Member and accession states are former Eastern Bloc members that transitioned from planned economies to market economies during the late 1980s and early 1990s. Half of the 14 have emerged from peaceful or violent separations of larger states and Cyprus has been divided in two since 1974 with the resulting political tension. As a result of these upheavals, many of these countries did not have the possibility or economic means to develop the necessary conditions to establish a healthy biotechnology sector until recently.

All of the 14 new EU Member States and candidate countries report a Gross Domestic Product (GDP)³ below the EU27 average but what is more significant is that it is not the wealthiest countries that have the most flourishing biotechnology sectors. The Czech Republic is 20% below EU27 GDP average, while both Poland and Hungary are around 40% below. Meanwhile, countries such as Cyprus and Slovenia, which demonstrate far less activity in the biotechnology field, are only 5 to 10% below EU27 average. This suggests that other factors such as existing infrastructures, the quality of academic institutions and a qualified workforce influence the growth and development of the biotechnology industry more than the capacity of funding alone. Furthermore, as the percentage of GDP allocated to R&D is much lower than the EU27 average it indicates that while governments may put research and high-tech development as national priorities, funds are allocated differently.

The availability of private funding from venture capital sources and angel investors in the 14 new Member States and candidate countries is extremely limited when compared to their Western neighbours. Many countries report an almost complete lack of private investor activity with the majority of funding coming from state or EU framework programmes and structural funds. This may be partially due to investors viewing this geographical area as risky and partially due to a lack of companies and projects advanced enough to attract investors with specific timelines and commitments to their shareholders. Until enough interest can be generated to attract private investors, the funding gap needs to be filled by national and EU public funding.

Support and Infrastructure

The majority of research and development throughout the 14 new Member States and candidate countries is conducted at universities or institutes and collaboration with industry is limited. The availability of quality premises for start-up businesses varies between the countries. Some countries, such as the Czech Republic, have established numerous technology parks and business incubators in an attempt to stimulate cooperation and interaction between high technology firms, while others such as Bulgaria are still in the process of planning such infrastructure. Clusters are also emerging in some of the 14

"Links between academia and industry are limited in all 14 states"

³ GDP data throughout this report is taken from Eurostat as surveyed in 2008, per inhabitant and expressed in purchasing power standards.

new EU Member and accession states, such as Poland and the Czech Republic.

The availability of professional and business advice is increasing but remains expensive. Some organisations exist to help new companies navigate the web of available public financing but their services are not affordable for many SMEs.

The region has also acquired the reputation for excessive bureaucracy and red tape. Many countries have actually made significant steps in reducing the procedure for starting a new company and, for example in Slovenia, the process can be completed relatively rapidly and mostly on-line. Yet some countries do still labour under heavy administrative burdens. Moreover, the mere perception that it is difficult or problematic to do business in a region can act as a deterrent for investors and entrepreneurs.

The Workforce

The majority of the 14 new Member States and candidate countries boast highly educated workforces at a fraction of the cost of labour in Western Europe. While this contributes to a favourable environment for foreign investment and the establishment of new firms, it also discourages young people from entering the scientific sector in favour of more lucrative careers and leads to a brain-drain of talented workers. Hungary, for instance, has clearly stated that it does not want to compete on the basis of low wages and has taken steps to attract back talented Hungarian scientists and managers. Nonetheless, the combination of skilled workers and low wages, coupled with the region's proximity to Western Europe, has contributed to the emergence of the region as a popular outsourcing destination.

Universities in the 14 new Member States and candidate countries generally offer a wide array of life-science courses, including specializations in biotechnology, and turn out quality graduates. However, graduates often lack industry experience and cooperation between academia and industry still needs to be developed and strengthened. Furthermore lack of opportunities coupled with poor financial compensation in scientific fields results in the diversion of promising students from the sciences to other fields such as economics and business.

Several countries such as Croatia also report a shortage of qualified management, making it difficult for SMEs and start-ups to fill key roles as they progress through the research and development process.

Technology and Intellectual Property

Although there is no shortage of innovative ideas in a region accustomed to carrying out research with limited funding, effective means of transferring innovation from academia to industry remain to be established. Scientists at academic institutes are focused on and rewarded for publishing their research with the purpose of obtaining grants for further research, while patenting and spinning-off or licensing their work is not encouraged. Technology transfer offices exist in some of the countries but are largely in the beginning stages of development and many scientists remain unaware of the legal framework around patenting their inventions. These factors may contribute to the low frequency of patent applications in the region compared with the EU27 average.

Nevertheless, in a process that began in the 1990s, led by Hungary, Poland, and the Czech Republic, the 14 Member States and candidate countries have been developing or modifying IP laws and regulations to adapt to EU standards.

"The region has a reputation for bureaucracy and red tape but many countries have made significant progress in reducing this burden"

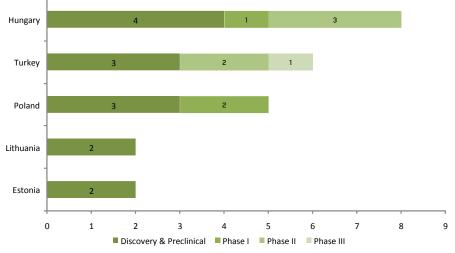
"Students are abandoning the sciences for more lucrative professions in economics and business"

Products in the Pipeline

Product Development Pipeline in the 14 New Member States and Candidate Countries

As information related to products in research and development is rather sensitive, few companies chose to disclose their therapeutic product pipeline. As can be seen from the available data, there are at least 18 therapeutic products in the pipeline, with the majority in the preclinical phase. However, as one can reasonably assume that companies formed with the purpose of developing human therapeutic biotechnology products would have at least one product under development; this number is likely to be higher. The products cover a variety of therapeutic areas including cancers, diseases of the skin and subcutaneous tissue, immune disorders and infectious diseases.

DEVELOPMENT CAPACITY INDEX



Therapeutic Product Development Pipeline in the 14 New Member States and Candidate Countries

Source: www.biotechgate.com

A Development Capacity Index (DCI) was developed as a means of representing the development status of a country in a format that allows comparison with other countries and regions. The resulting value indicates the respective countries' relative rank among their peers and considers both the existing state of affairs (represented by the quantitative factor) as well as the potential for development (represented by the qualitative factor). The calculation of the DCI is detailed in appendix A.

Both qualitative and quantitative factors were considered for each country. The assessment for the qualitative factor includes the level of government support, the availability of a qualified workforce, the advancement of technology transfer

systems, the awareness of IP protection, the existence of technology parks and clusters, the level of public and private financial support and the presence of a pharmaceutical industry. The calculation of the quantitative factor is based on the number of biotechnology companies present, their category of activity (therapeutics, services and other biotechnology sectors), and the number of products under development. Parameters are all individually measured with emphasis placed on smaller and medium sized companies conducting research on human therapeutics, as these are considered to be the drivers of innovation for the industry. A higher DCI indicates the presence of a more advanced biotechnology industry and a more favourable environment for future growth.

It needs to be underlined that the DCI is a tool for the assessment and comparison of the biotechnology development status and potential of a country at a certain point in time, based on available data.

A thorough analysis of a country's potential needs to consider an evaluation of DCI evolution over time and an analysis of the country's specific strengths and weaknesses as presented in the 'Country Reports' in the following chapters.

The summarized DCI values and qualitative factor for each new member country are as follows:

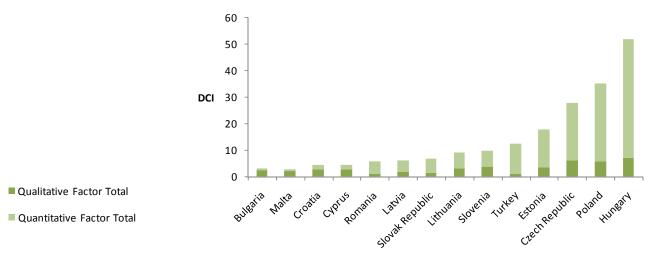
NOTE: The DCI is the sum of the qualitative and quantitative factor, divided by 10 for ease of representation.

Country	Qualitative Factor Total	Quantitative Factor Total	DCI
Bulgaria	24	6	3
Malta	20	7	3
Croatia	25	19	4
Cyprus	28	17	5
Romania	10	47	6
Latvia	18	42	6
Slovak Republic	14	52	7
Lithuania	31	59	9
Slovenia	38	58	10
Turkey	10	115	12
Estonia	33	144	18
Czech Republic	59	217	28
Poland	56	295	35
Hungary	69	449	52

When the DCI is represented as a variable of the quantitative and qualitative

factors, in the resulting graph, countries appearing in the upper part of the following graph can be considered to have relatively more developed frameworks and policies contributing to a more positive environment for the future development of the biotechnology sector. Countries appearing farther to the right part of the graph currently have more companies and employees engaged in the biotechnology sector.

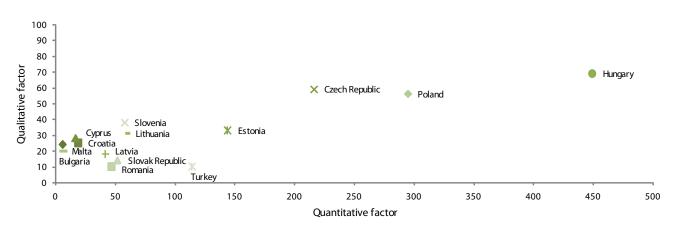
When the DCI is adapted to consider the population of the country, a shift to the right can be observed for smaller countries while larger countries shift to the left. As the qualitative factor is calculated on a per country basis it is



DCI in the 14 new Member Sates and Candidate Countries

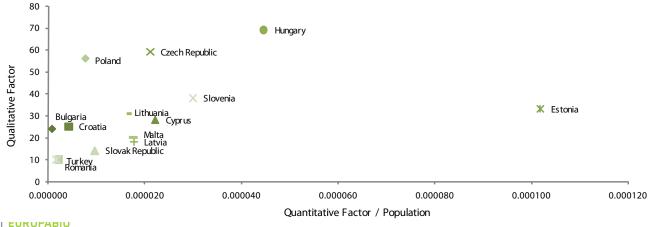
not influenced by population. Taking into account population differences shows that some countries, such as Estonia, have managed to establish a significant

Quantitative and Qualitative Factors in the 14 new Member Sates and Candidate Countries



biotechnology sector in per capita terms. Nevertheless per capita measurement of the biotechnology industry is not significantly indicative of future success, as it is the achievement of a critical industry mass, independently of the country's size, that ultimately determine the success of the sector. This phenomenon can, for example, be observed in Switzerland, which supports a thriving biotechnology and pharmaceutical sector with a relatively small population.

Quantitative and Qualitative Factors in the 14 new Member Sates and Candidate Countries (quantitative factor adjusted for population)



APPENDIX A: CALCULATION OF THE DCI

The Development Capacity Index (DCI) was developed as a means of representing the development status of a country in a format that allows comparison with other countries and regions. The resulting value indicates the respective countries' relative rank among their peers and considers both the existing state of affairs (represented by the quantitative factor) as well as the potential for development (represented by the qualitative factor). A higher DCI indicates the presence of a more advanced biotechnology industry and a more favourable environment for future growth.

Evaluation of the Qualitative Factor:

The qualitative factor was used to evaluate the framework available for the development of the biotechnology sector. Factors considered were existence of a pharmaceutical industry, level of government support, availability of public and private financial support, existence of a qualified workforce, establishment of technology transfer offices and technology parks, and general awareness of patenting and IP protection processes.

As shown in the following table, each factor was assigned a weight based on the subjective assessment of its relative importance for the evaluation of a countries development potential. Each factor was then evaluated for each country based on information gathered from literature, and interviews with local stakeholders and companies. A rating was assigned for each factor ranging from 0 (non-existent) to 4 (excellent) and individual ratings were summed to give the total qualitative factor for that country.

QUANTITATIVE FACTOR	WEIGHTING	RATING	POINTS	WEIGHTED POINTS
Pharma		Non-existent	0	0
Industry		Minimal	1	2
-	2	Average	2	4
(exiting know-		Good	3	6
how)		Exceptional	4	8
		Non-existent	0	0
Government		Minimal	1	2
	2	Average	2	4
Support		Good	3	6
		Exceptional	4	8
		Non-existent	0	0
Public Financial		Minimal	1	3
	3	Average	2	6
Support		Good	3	9
		Exceptional	4	12
	3	Non-existent	0	0
Private		Minimal	1	3
Financial		Average	2	6
Support		Good	3	9
		Exceptional	4	12
		Non-existent	0	0
Oualified		Minimal	1	3
Workforce	3	Average	2	6
WUIKIUILE	4	Good	3	9
		Exceptional	4	12
		Non-existent	0	0
		Minimal	1	4
Tech Transfer		Average	2	8
		Good	3	12
		Exceptional	4	16

			6	6
Tech Parks or Clusters	4	Non-existent	U	0
		Minimal	1	4
		Average	2	8
		Good	3	12
		Exceptional	4	16
IP Protection Awareness	4	Non-existent	0	0
		Minimal	1	4
		Average	2	8
		Good	3	12
		Exceptional	4	16

Evaluation of the Quantitative Development Factor:

The quantitative factor was calculated based on the number of biotechnology companies present, their category of activity (therapeutics, services and other biotechnology sectors), and the number of products under development. Parameters were all individually measured with emphasis placed on smaller and medium sized companies conducting research on human therapeutics, as these are considered to be the drivers of innovation for the industry.

Within each country, points were assigned per company depending on the type of company, number of employees, products on the market and products in development, as shown in the following table. Fewer points were attributed to products on the market as this is an indication of existing industry and knowhow, whereas the development of new products indicates the potential for growth.

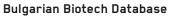
It is to be noted that few companies chose to disclose their product information therefore these parameters have only a small impact on the overall DCI. It was assumed that all biotechnology companies developing therapeutics had at least one product in the pipeline.

Factor	Points
Biotechnology therapeutics company	5
Biotechnology services company	1
Other biotechnology company	3
<10 employees	5
10-100 employees	4
100-500 employees	3
500-1000 employees	2
> 1000 employees	1
no data or 1 product in development	1
2 products in development	2
3 products development	3
4 products development	4
5 or more products development	5
1-2 products on the market	0.25
3-5 products on the market	0.5
5-10 products on the market	0.75
10-20 products on the market	1
more than 20 products on the market	1.25

Points calculated for all companies in the country were then summed to give the total quantitative factor for that country.

APPENDIX B: PROJECT PARTNERS

Bulgaria



www.bulgarianbiotech.com

The Bulgarian Ministry of Education, Youth and Science pursues overall policy development in education, youth initiatives and research. The Department for Scientific Research and Projects facilitates the implementation of research policy and programming by the minister. Activities include financing and supporting implementation of scientific research, evaluating the obtained results as well as organizing and promoting international collaboration. These activities are directed towards establishing, improving and updating the existing regulatory and information database of research project funding, research evaluation and execution of National Scientific programmes. Bulgarian National Research Programmes are developed in relevance with the European thematic areas of FP7: Genomics, Information Society, Nanotechnology and New Materials. (http://www.minedu.government.bg)



Croatia



Croatian Biotech Database

www.croatianbiotech.com

Based in Samobor, Croatia since 1993, FARMAVITA d.o.o. is active in pharmaceutical business development, licensing, technology transfer and regulatory affairs, in central-east and south-east Europe. Farmaviat.Net manages a number of regional associates and facilitates a dynamic network of over a thousand members / pharmaceutical companies interested in license-in and license-out opportunities, alliances, joint ventures, co-development and co-marketing of pharmaceutical products. (http://www.farmavita.net/)

Farmavita.Net

Cyprus



Cypriot Biotech Database

www.cypriotbiotech.com

Founded in 1996, the Research Promotion Foundation (RPF) was established as an initiative of the Government of the Republic of Cyprus, to promote the development of scientific and technological research. The Foundation is an independent organization governed by a twelve-member Board of Directors, appointed by the Council of Ministers for five years. (http://crpf.metacanvas. com/EN/)



Czech Republic



Czech Biotech Database www.czechbiotech.com

Gate2Biotechnology was created by the South Moravian Innovation Centre with the support of CzechInvest. Gate2Biotechnology aims to develop the biotechnology sector in the Czech Republic and facilitate communication nationally and internationally through networking. (http://www.gate2biotech.cz/)



The aim of the South Moravian Innovation Centre (Jihomoravske inovacni centrum, abr. JIC) is to create complex infrastructure for support of innovative entrepreneurship in the South Moravian region and to become the main provider of support for start-up innovative companies in Europe.



JIC supports innovative companies, science, research and students with original ideas by providing them with money, consultancy, contacts and spaces. JIC was founded in 2003 as an association of legal entities with related interests. Its founders are the South Moravian regional authority, Statutory City of Brno, Masaryk university, Brno University of Technology (BUT), the Mendel University of Agriculture and Forestry and Veterinary and Pharmaceutical University in Brno. (http://www.jic.cz)

Estonia



Estonian Biotech Database www.estonianbiotech.com

Hungarian Biotech Database www.hungarianbiotech.com

The Estonian Biotechnology Association (EBio) was founded in 2003 by 15 biotechnology companies and organizations. Currently, EBio consists of 32 members, both enterprises as well as research institutions. The purpose of EBio is to represent the Estonian biotechnology sector both within and outside of Estonia, and to support the development of the industry. EBio organizes events, represents its members at exhibitions and conferences and in communication with state institutions, creates contacts for networking and mediates information. (www.biotech.ee)

Hungary



leading biotechnology companies with the aim of promoting the development and representation of the Hungarian biotechnology sector. The Association's major objectives include obtaining support for the continued development of national life sciences and the commercialization of scientific achievements as well as representing both Hungary and its members at international exhibitions and conferences. Currently, the Hungarian Biotechnology Association has around one hundred members. (www.hungarianbiotech.org)

The Hungarian Biotechnology Association (HBA) was established by Hungary's

The Hungarian Investment and Trade Development Agency (ITD Hungary), was founded in 1993 by the Hungarian Ministry of Economy and Transport (now: Ministry of National Development and Economy) to help implement the government's investment and trade promotion policies.



ITD Hungary's mission is to help Hungarian small and medium-sized enterprises strengthen their position in the global market by fostering entrepreneurial spirit, promoting regional development and expanding international relationships. The agency also actively facilitates the investment process and encourages the import and export of capital with the goal of playing an active role in generating added value and building a knowledge-based society in Hungary. (www.itd.hu)

Latvia

Latvian Biotech Database

www.latvianbiotech.com

The Latvian Biotechnology association (LBA) was created as the first Latvian biotechnology network in 2006. The country's long experience and traditions, the availability of highly gualified specialists, cost efficiency, high competence in R&D and a developing manufacturing base are the factors that form an excellent foundation for business and innovative activities in Latvia's biotechnology sector.

The main aim of the LBA is to promote the development of biotechnology in Latvia by clustering academia, governmental bodies and industry in joint projects, by participating in international projects, by representing their members in meetings and exhibitions, by promoting education of young specialist in biotechnology and related fields, and by raising public awareness of biotechnology.

Several of the initiators behind the LBA are already involved in the network of ScanBalt www.scanbalt.org .

LBA is a member of the European Federation of Biotechnology and ScanBalt network. (www.latbiotech.lv)

Lithuania

Lithuanian Biotech Database

www.lithuanianbiotech.com

Founded in 1975 as the all Union Research Institute of Applied Enzymology, currently the Institute of Biotechnology is mainly involved in research and training in the fields of biotechnology and molecular biology, including research and development of recombinant biomedical proteins, genetic and molecular studies of restriction modification phenomenon, developing of virus diagnostics, epigenetic study of small RNA, drug design and synthesis, and bioinformatics. The Institute of Biotechnology is a member of Lithuanian Biotechnology Association. Association (http://www.ibt.lt/)

Lithuanian Biotechnology Association (LBTA) was founded in 2003 with the purpose of representing Lithuanian biotechnology companies and research institutions and organizing actions that stimulate progress of the biotechnological sector. LBTA prepared the Programme on the Development of Industrial Biotechnology in Lithuania for 2007 - 2010, that was approved by the Government (2006), and founded the Lithuanian Biotechnology Platform (2007). The National Integrated Programme of Biotechnology and Biopharmacy was prepared together with the Institute of Biotechnology and Lithuanian Association of Pharmaceutical Industrial Enterprises (2008). (www.lbta.lt)

Malta



www.maltesebiotech.com

Malta Enterprise is the national agency responsible for the promotion of foreign direct investment, trade and industrial development in Malta. Its mission is to sustain Malta's overall competitiveness and to create the right environment for successful enterprise in Malta. Within this context Malta Enterprise follows the









national strategy for research and innovation which aims to build and sustain the necessary framework to attract research and innovation (R & I) related projects.

Malta Enterprise is promoting a Life Science Centre which is co-financed through European Regional Development Funds. This project epitomizes the Government's commitment towards the creation of a dynamic high value-added, technology intensive, knowledge based economy, in line with Vision 2015. (http://www.maltaenterprise.com/)

Poland



Polish Biotech Database www.polishbiotech.com

Wroclaw Technology Park (WPT) is an innovative centre for dynamically developing companies involved in research. Its objective is to stimulate the advanced technologies industry by delivering proper infrastructure to ensure that companies have good conditions to do business.

WPT supports firms conducting research in biotechnology, chemistry and other related branches. The technology companies located in WPT have easy access to the Laboratory and Prototype Workshop for Biotechnology Processes, which is outfitted with modern equipment and devices. The Laboratory is adjusted to performing: Foodstuffs chemical analysis, lonic and Non-ionic Surface - Active Agents Physicochemical Analysis, Utilizable Formulae Analysis, Spectral Analysis of Poliphenolic Compounds in Foodstuffs and Cosmetics, Cosmetic Formulae Design within the Context of Composition Optimalization and Physicochemical Stability, HPLC and GC Qualitative and Quantitative Analysis, New Technology Design and the Refinement of the Existing Chemical and Biotechnological Processes.

In a friendly environment and creative atmosphere companies can cooperate with one another and realize common projects. (www.technologpark.pl)



CHNOLOGY

PARK

LifeScience Cluster Krakow EIT+ WRC (Wroclawskie Research Centre) aims to create a knowledge-based economy in Lower Silesia by promoting science, innovation and education. EIT+ focuses on innovative technologies such as nanotechnology and advanced materials, biotechnology and advanced medical technologies and information and communication technologies. The company also represents scientists striving to apply their discoveries and research results in industry. (http:// www.wcb.eitplus.pl)

The LifeScience Cluster Krakow was established in 2006 as a collaborative project of institutions from science and education, business, health care and government, which actively engage in cooperation at the regional level to (a) support innovation and encourage effective commercialization of research results in the biotechnology and life science field and (b) develop resources and competences in the life science sector in order to effectively explore existing and future opportunities related to development of a knowledge-based economy. (http://www.lifescience.pl)

Romania

Romanian Biotech Database

www.romanianbiotech.com

Founded in 1960 as a research-design institute for automation, IPA SA focuses on research and development, design, production, assembling, service and consultancy for automation and IT systems as "turn-key solutions" across numerous industries. The company has strong relations with SMEs, Universities, R&D Institutes, local administration and provides services for the benefit of SMEs, business incubation and technology transfer activities. (http://www. ipacv.ro)

The National Centre for Programme Management (CNMP) is a legal Romanian public body established by the Government Decision to coordinate research programmes owned by the MEdR (MERI - ANCS) and to coordinate the research programmes under the National Plan(s) for Research, Development & Innovation.

The CNMP's activity as programme manager entails preparation of calls for proposals, organization of independent evaluation of proposals, contract negotiation, scientific and financial monitoring of (projects based) programmes and evaluation of programme implementation, results and impact.

The CNMP has been assigned by the Ministry of Education, Research and Youth / The National Authority for Scientific Research (ANCS), to manage the R&D Programme "Partnerships in Priority R&D Areas" - 2nd National Plan for Research, Development & Innovation (2007-2013). The R&D Programme ""Partnerships in Priority R&D Areas" is structured in nine thematic areas, similar to FP7: Information and Communication Technology, Energy, Environment, Health, Agriculture, food safety and security, Biotechnologies, Innovative materials, processes and products, Space and security, Socioeconomic and humanistic research. (http://www.cnmp.ro)

The Romanian Society of Biotechnology and Bioengineering (RSBB) is a scientific, non-governmental professional organization of people working in the bioscience field (research, industry and education) in Romania. RSBB is a not for profit, autonomous and independent body, comprised of about 250 members from Romanian Universities, research Institutes and bio-industrial companies. The organization was founded in 1990 and has been affiliated with the European Federation of Biotechnology (EFB) since June 1993.

The objective of RSBB is to promote safe and ethically acceptable biotechnology for the better use of natural resources and to advance biotechnology and bioengineering as interdisciplinary fields of work and to support their scientific, economic and applied technical development. (www.srbb.ro)

The Pasteur Institute was founded within the Faculty of Veterinary Medicine in 1895, as an Institute of Animal Vaccines. Today the Pasteur Institute is involved in areas of research and development concerning animal health, environment protection, animal welfare, public veterinary hygiene, epidemiology and diagnosis and especially pharmaceutical production.

We are especially thankful to Dr. Mihai Danes from the Pasteur Institute who gave us relevant information about the state of the biotechnology industry in Romania. (http://www.pasteur.ro)









The Slovak Republic



SLOVBIOTECH





www.slovakbiotech.com

MarkOffice offers consultation in all matters related to protection of patents, trademarks, designs, utility models, and other intellectual properties in Slovakia and in the European Union. MarkOffice resides in Banska Bystrica, Slovak republic, seat of the Office of Industrial Property of the Slovak republic.

The company was founded in 2002 by Ivan Belicka, the former head of the National Trademarks Department at the Slovak Industrial Property Office, who is a professional representative before the OHIM (No. 28174) and a European Patent Attorney (No.133070). The company's aim is to represent its client's administration in all matters of intellectual property. (http://www.markoffice.eu)

The Slovak Association for Industrial Biotechnology was established in 2006 and has 15 industrial and academic members. The mission of the Association is to support the development of biotechnology in Slovakia. The main objectives and priorities are to support and protect the interests of industrial enterprises whose production is based on industrial biotechnology, and to cooperate with governmental and international institutions and organizations in the formation of conditions for biotechnological research and production. (http://www.stuba. sk)

The Slovak Research and Development Agency (SRDA) was established by the Slovak Parliament Act in July 2005 as the research and development grant agency. SRDA is the instrument for distribution of public finances for research and development on a competitive basis in the Slovak Republic. The SRDA is responsible for basic and applied research and development promotion in all research fields, including international research cooperation.

The Agency supports the participation of research and development organizations in the Slovak Republic in European programmes and research and development initiatives. As well, the SRDA supports active participation of Slovak researches in the 7th European Framework Programme. (http://www. apvv.sk)

Slovenia



Slovenian Biotech Database www.slovenianbiotech.com

The Public Agency for Technology of the Republic of Slovenia (TIA) is an independent public agency responsible for the enhancement of technology development and innovation in the Republic of Slovenia. Main activities include grant programmes aimed at technology development and fostering cooperation of R&D institutions and universities with industry. The Agency implements programmes and measures to promote competitiveness and technological development; plans, directs and finances activities for the promotion of innovation and R&D activities and the transfer of knowledge; provides advice and technical support to promoters of projects for the development of products, production processes and services in obtaining information and financial resources; promotes cooperation and the transfer and application of international technological knowledge; promotes connections and the transfer of knowledge between R&D institutions and industry. (http://www.tia.si)

Turkey

Turkish Biotech Database

www.turkishbiotech.com

The Turkish Biotechnology Association was established in 1986 with the mission to make biotechnology development a part of state policy in Turkey. The Biotechnology Association is an institutional member of the European Federation of Biotechnology and represents nearly 400 members country-wide. Members are generally scientists and industrial employees that study in the agricultural biotechnology, industrial biotechnology, food biotechnology, medical biotechnology, pharmaceutical biotechnology and environmental biotechnology branches. The Biotechnology Association facilitates coordination between biotechnology industry employees and scientists and organizes national and international congresses, symposiums and conferences to increase the flow of information. (http://www.biyoteknoloji.org.tr/indexENG.html)



APPENDIX C: DEFINITIONS

The definition and categorisation of biotechnology companies is complex. For this report, it was decided to use a categorisation system developed over the last 6 years for the Global Biotechgate Database which has also been used for leading partnering conferences. Currently over 15'000 companies worldwide have been recorded in this system.

Biotechnology companies are those that employ living organisms or biological substances for the development of products and services with applications in numerous fields such as waste management, food processing, agriculture and pharmaceutics. The system allows for both a very narrow definition of biotechnology, focusing on therapeutic companies, often referred to as Red Biotech. The other two main biotechnology categories in the Biotechgate database are 'Biotechnology - R&D Services' and 'Biotechnology - Other' which includes companies such Agribiotech, Nutraceuticals, Veterinarian, Industrial Biotechnology and others.

The definitions of these three categories, and the activities or products within each category are detailed below.

BIOTECHNOLOGY - THERAPEUTICS

Companies categorized as Biotechnology-Therapeutic are those whose core business is the application of biotechnology to the discovery and development of novel therapeutic compounds for applications in medicine.

Antibodies: Companies whose primary research area is the production of antibodies.

Anti-infectives: Companies whose primary research area is anti-infective compounds such as antibiotics.

Biosimilars: Companies whose primary research area is biosimilars, also called follow-on biologics, which are officially-approved new versions of existing biopharmaceutical products.

Cell therapy: Companies that specialize in the replacement of diseased cells and tissues with healthy cellular material.

Drug delivery: Companies that specialize in developing compounds that deliver or improve the delivery of medicines to targeted areas in the body.

Gene therapy: Companies that specialize in the treatment of a disease by introducing a new gene into a cell through the use of recombinant DNA technology. The new gene may be used to replace a function that is missing because of a defective gene or to treat a genetic disorder.

Generics: Companies whose primary research area is generic medicines which are drugs that are chemically equivalent to a particular medicine, innovated by another company, on which the patent has since expired.

Nucleic acid drugs: Companies that specialize in developing nucleic acids that act as drugs for inhibiting gene expression or protein synthesis.

Peptides: Companies that specialize in developing peptide based drugs.

Proteins: Companies that specialize in developing protein based drugs.

Small molecules: Companies that specialize in developing small molecule

compounds.

Stem cells: Companies that specialize in the use of stem cells as a therapeutic or to repair specific tissues or to grow organs.

Vaccines: Companies whose primary research area is the development of vaccines either for disease therapy or prevention.

Other: Therapeutic biotechnology companies specialized in an area not mentioned above.

BIOTECHNOLOGY/ R&D SERVICES

Companies that fall under the biotechnology / R&D Services category are those that provide support services such as product development services, analytical services, screening, contract manufacturing and contract R&D to the biotechnology industry.

Analytical services: Companies that provide analytical services.

Biochips: Companies that produce biochips for other companies to use in their development process.

Bioelectronics: Companies that produce bioelectronics for other companies to use in their development process.

Bioinformatics: Companies that provided bioinformatics services such as the analysis of biological information using computers and statistical techniques.

Cell culture: Companies that culture cells for other companies to use in their development process.

CMO (Contract Manufacturing Organization): Companies that take-over the manufacturing responsibilities for another company.

CRO (Contract Research Organization): Companies that conduct research for other companies on a contract basis.

Diagnostic instrumentation: Companies that develop diagnostic tests and kits.

Diagnostic services: Companies that carry out diagnostic test for other companies.

Drug delivery: Companies that research and develop methods of drug delivery for other companies.

Fill & finish: Companies that provide fill and finish services.

Genomics: Companies that study and define nucleotide sequences, including genes, regulatory sequences, and noncoding DNA segments, for other companies.

Proteomics: Companies that identify and modify proteins for other companies to use in their development process.

Screening: Companies that screen potential therapeutic compounds for other companies by performing various test and assays.

Synthesis services: Companies that synthesize molecules for other companies.

Other: Companies that provide other support services to biotechnology companies.

BIOTECHNOLOGY - OTHER

Companies that fall under the biotechnology - Other category are all of those that apply the concepts of biotechnology (using living organisms or biological substances for the development of products and services) to areas other than drug development for medical use. Examples of areas covered under biotechnology - other are Agribio companies, cosmetic companies, environmental companies, food technology companies, industrial biotechnology companies, nutraceutical companies and veterinary companies.

AgriBio: Companies that apply the principles of biotechnology to agricultural uses such as the production of pesticides or extension of fruit and vegetable shelf life.

Cosmetics: Companies that apply the principles of biotechnology to the production of cosmetics.

Environmental: Companies that apply the principles of biotechnology to the protection and restoration of the environment through processes such as waste water treatment and clean energy production.

Food: Companies that apply the principles of biotechnology to the production and processing of food.

Industrial Biotechnology: Companies that apply the principles of biotechnology to industrial processes.

Nutraceuticals: Companies that develop natural products for a therapeutic purpose.

Veterinary: Companies whose primary product area is are cantered on the diagnosis and treatment of diseases and injuries of animals, particularly domestic animals.

Other: Companies that apply the principles of biotechnology in an area not mentioned above that does not involve therapeutic medicine or the provision of a service.

APPENDIX D: METHODOLOGY

The main objectives of the 14allbio project were:

- To design and create self service software for the collection of data in the 14 new Member States and candidate countries
- To market the data collection system to the biotechnology community and collect information in the 14 new Member States and candidate countries
- To validate and analyse the findings and propose policy recommendations
- To disseminate the results among critical stakeholders in the European Community.

The objectives were achieved with the indispensable assistance of local partners (see Appendix B) and companies operating in the 14 new Member States and candidate countries.

Initially a database was created for each state (See Appendix B) and partners were sought in each country to assist with gathering information about life science companies operating in the area. The database was then populated with the available company information and a web-based marketing campaign was launched to encourage use of the databases.

Each company in the database was then contacted by telephone to complete missing information and verify existing data. The data, as well as information form surveys of partners and companies, was then compiled into this report. It is important to note that not all companies chose to disclose information, particularly related to sensitive topics such as revenues and products in development; therefore the data in the report is based on the information that was available.

Dissemination was achieved through the organisation of four presentation workshops in Hungary, Lithuania, the Czech Republic and Belgium and the distribution of the report through partner networks.

SOURCES

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Prepared by:





www.venturevaluation.com

Information about the project can be found at www.14allbio.eu

All company details and data are available on:



www.biotechgate.com

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