



Biotechnology Report

BULGARIA

PREPARED BY EUROPABIO AND VENTURE VALUATION IN 2009

STATUS OF THE BULGARIAN BIOTECHNOLOGY SECTOR

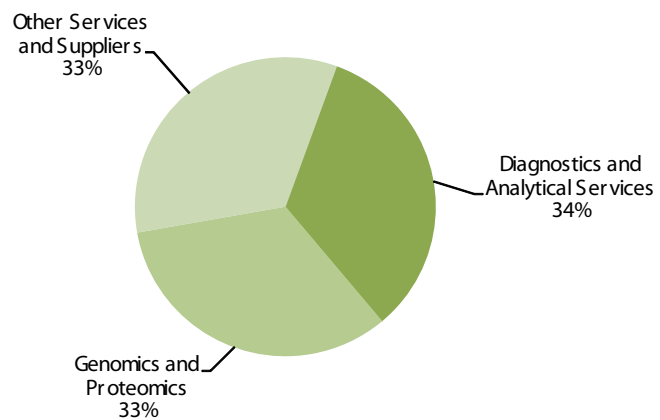
(Financial data in €)

1	Total Biotech Companies
0	Biotech-Therapeutic
1	Biotech-Services
0	Biotech-Other
40	Employees
3	R&D employees
NA	R&D spending
NA	Revenue
NA	Equity Raised
NA	Government grants
100%	Percentage of SMEs
0	Percentage of companies publicly owned

Currently Bulgaria hosts only one Biotechnology-Services company, which, with less than 250 employees, qualifies as an SME. The company was founded in 1998 and is a representative of Roche for Bulgaria.

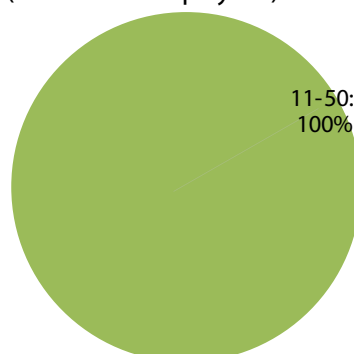
Biotechnology Companies in Bulgaria

Breakdown by Subcategory based on 3 entries by 1 company



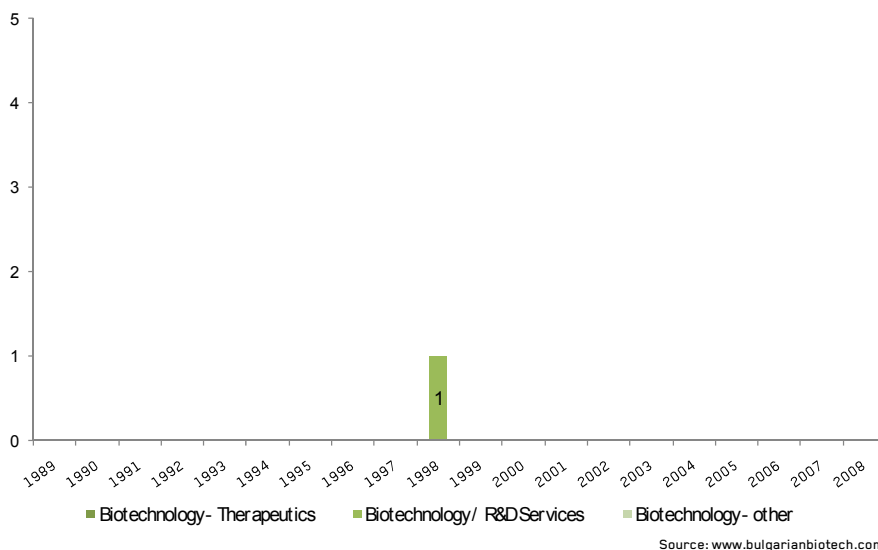
Source: www.bulgarianbiotech.com

Biotechnology Company Size in Bulgaria (number of employees)



Source: www.bulgarianbiotech.com

Company Foundations in Bulgaria



BULGARIA – AN INDUSTRY OVERVIEW

Bulgaria established a strong pharmaceutical and biotechnology sector with support from the socialist government in the 1980's; however, during the reforms this industry almost completely collapsed and has only recently begun to recover.

There is no biotechnology association in Bulgaria but pharmaceutical manufacturers are represented by two associations.

Political and Economic Environment

The government does not have clear and established research priorities and the research strategy is currently under development but biotechnology has been identified as a main area of interest.

The Ministry of Education and Sciences operates the National Fund for Scientific Research which is responsible for the majority of research and development funding in Bulgaria. Additionally, the Ministry of Economy and Energy established the National Innovation Fund in 2005, with an initial budget of €2.5 m, to promote links between the private and public sector and support commercially oriented research and development.

The majority of R&D funding (about 70-75%) comes from the national budget and a large part is allocated in lump sums to institutes. There is, however, a growing trend towards installing a competition-based system for obtaining funds via the National Fund for Scientific Research. Grants are now provided for research infrastructure developments that require a minimum of three different types of organizations to be involved and financially contribute to the project in order to receive funding. The balance of funding is made up by the EU and limited private sources; however, all the available funding amounts to a very low and insufficient sum well below the EU average.

Hospitals in Bulgaria are considered private entities and are also eligible to contribute financially to R&D projects to encourage clinical trials and application of research results.

Venture capitalists and business angels are not well established in Bulgaria. In 2008 a special bank was created to provide schemes for venture capital

funding although no known schemes have been implemented to date.

There is a particularly restrictive view on GMO research in the country with all such types of research projects being required to pass through the Ministry of Health ethical committee and few receiving approval.

Support Infrastructure

Traditionally, under the former Socialist government, research and development was carried out in independent research organisations usually attached to the Bulgarian Academy of Sciences. Recently some universities, particularly the large medical universities, have also developed their own strong research facilities.

There are no science and technology parks in Bulgaria. In 2007, six technology transfer offices were established under schemes funded by the Innovation Fund; however, no results can yet be reported.

While there is still some red tape surrounding the administrative process of establishing a new entity, this administrative burden has eased since the application of EU legislation. The favourable corporate tax rate of 12% is intended to encourage the formation of new companies; however, a facilitated procedure for establishing innovative companies or start-ups is still lacking.

The workforce

Several universities, including Sofia University, offer a variety of life science courses at high levels but, as in many new Member States, there is a shortage of young people pursuing a research career. Recently there has been a dramatic shift of students from the sciences to business studies due to a lack of career opportunities in the sciences.

There is no link between higher scientific studies at the universities and industry and in many cases university Professors are only lecturers and do not simultaneously undertake research. The universities lack modern research equipment and there are no established interactions between students and industry during the term of study. Schemes are beginning to emerge under the National Fund for Scientific Research to improve the connection between academia and industry by establishing project based doctoral degrees and post doctoral fellowships and there is an initiative under the Operative programme for the "Development of Human Resources".

Technology and intellectual property

Awareness of intellectual property and patenting is high in Bulgaria and there is adequate legislation in place. The ownership of a patent is split between the employing institution, the employee and, if applicable, the funding institution. There are however not enough patentable research products or technologies available and the high cost of maintaining a patent is prohibitive for most SMEs. As a result, 90% of SMEs in Bulgaria provide services instead of investing in product research and development.

Publication rates are low compared with other new Member States and citation rates are even lower.

"90% of SMEs in Bulgaria provide services instead of investing in product research and development"

Products in the Pipeline:

There are currently no therapeutic biotechnology products under development in Bulgaria.

DEVELOPMENT CAPACITY INDEX

The development capacity index was calculated for Bulgaria according to the description in Appendix A and can be used to compare the status of the Bulgarian biotechnology sector with that of the other new Member States and candidate countries. It consists of a qualitative factor of 24 and a quantitative factor of 6.



KEY FEATURES

3 positive key features:

- **The institutional landscape is well developed**
- **Biotechnology is recognised as a main area of interest**
- **Awareness of intellectual property and patenting is high**

3 negative key features:

- **Private funding available for R&D is very limited**
- **Cooperation between academia and industry is limited**
- **There is a lack of facilitated procedures for establishing innovative companies and start-ups**

In Bulgaria, considering that a good innovation framework is in place, increasing funding for initial research would have the most impact in the development of biotechnology.

SOURCES

The Bulgarian Biotechnology Database (www.bulgarianbiotech.com) part of the global Biotechgate database (www.biotechgate.com)

Survey from the Bulgarian Ministry of Education and Science; 2008

Company interviews; 2008-2009

BioPolis - Inventory and analysis of national public policies that stimulate research in biotechnology, its exploitation and commercialisation by industry in Europe in the period 2002-2005 - National Report of Bulgaria; March 2007



In collaboration with:



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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 the 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 country's 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.

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

Tech Parks or Clusters	4	Non-existent	0	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 know-how, 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.

Prepared by:



The European Association for Bioindustries

www.europabio.org



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