THE BIOTECHNOLOGY SECTOR IN POLAND

PAI

Polish Information and Foreign Investment Agency
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1. General condition of biotechnology in Europe

Europe's biotech industry, after years of consolidation and relatively stagnant results, is decisively back on track. The industry's performance in 2005 was much better on several fronts compared to performance in 2004.

- The overall industry achieved a growth rate of 7%, bringing the sector's revenues to a new high of EUR 11.7 billion.
- R&D expenses increased by 22% for publicly traded companies and by 15% for the industry as a whole.
- The number of biotech companies in Europe decreased by about 3%, but this was mainly because of a significant increase in acquisitions.
- Total employment in Europe's biotech sector increased by 3%.
- There was a significant increase in the number of IPOs.
- There was a 38% increase in the number of products that were brought to market.

The United States is still the world leader in the biotech sector. One of the main reasons that European firms are less competitive in the international market is insufficient financing of the European biotechnology sector.

2. Comparison of biotechnological industry potential in the US and the EU

<table>
<thead>
<tr>
<th>BIOTECH INDUSTRY IN 2005</th>
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</thead>
<tbody>
<tr>
<td><strong>Revenues (USD million)</strong></td>
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<tr>
<td>47,790</td>
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<tr>
<td><strong>R&amp;D expenses (USD million)</strong></td>
</tr>
<tr>
<td><strong>Net profit (loss) (USD million)</strong></td>
</tr>
<tr>
<td><strong>Number of companies</strong></td>
</tr>
<tr>
<td><strong>Private companies</strong></td>
</tr>
</tbody>
</table>

Source: Compiled on the basis of data from Ernst & Young (Beyond Borders: The Global Biotechnology Report 2006)

3. Future of the European biotech industry

- The Framework Programme (FP) is the European Union's main instrument for funding research and development. The current FP is FP6, which runs until the end of 2006.
- The Seventh Framework Programme (FP7) will be fully operational as of 1 January 2007 and will expire in 2013. It is designed to build on the achievements of its predecessor towards the creation of the European Research Area, and carry it further towards the development of the knowledge economy and society in Europe.

- According to the Commission proposal the maximum overall amount for Community financial participation in the EC Seventh Framework Programme should be EUR 72,726 million for the period 2007-2013. The proposed Seventh Framework Programme will be organised in four programmes corresponding to four basic components of European research:
  1. Cooperation
  2. Ideas
  3. People

- FP7 presents strong elements of continuity with its predecessor, mainly as regards the themes which are covered in the Cooperation programme. The themes identified for this programme correspond to major fields in the progress of knowledge and technology, where research must be supported and strengthened to address European social, economic, environmental and industrial challenges.
- Among nine high-profile themes proposed for EU action in the Cooperation programme is the sub-programme Food, agriculture and biotechnology. EUR 44,432 million is to be distributed for the activities included in the Cooperation programme.

4. The 6th Framework Programme of the EU – Poland and EU Member States

- The biotech industry's performance in 2005 was strong around the world but the United States still led the way.

5. Biotechnology sciences in Poland

There are three segments of biotechnology in Poland (according to OECD and EU classification):

- green biotechnology – biotechnology connected with agriculture (including for example agri-food and crop biotechnology);
- red biotechnology (medical biotechnology) – biotechnology used in healthcare and health protection;
- white biotechnology – industrial biotechnology that uses biological systems in industrial output and environmental protection (environmental biotechnology).

Polish biotechnology is at an early stage of development with the leading role played by the medical and pharmaceutical sectors. A strong tradition in science provides an opportunity for creation of a fully developed modern biotechnology industry in Poland. The most favourable factors for the development of the biotech sector in Poland are:

- Application of biotechnology techniques in environmental engineering, production of drugs and vaccines, and gene therapy is supported by the public.
- Biotechnology-related legislation complies with European Union regulations.
- The knowledge and expertise of Polish scientists meet Western standards. Poland has a long-standing tradition of excellence in classical synthetic and mechanistic chemistry, theoretical physics, mathematics and informatics.
- Transfer of biotech know-how is facilitated by the participation of Polish researchers in numerous international initiatives.
- The number of students graduating with biotechnology degrees is rapidly increasing.

Development of all segments of biotechnology in Poland requires investment in infrastructure. This is essential for the emergence of new technologies and new products. There is great scientific potential in Poland as far as biotechnology is concerned, and it needs to be further expanded for more dynamic growth in the Polish economy. There are plenty of excellent ideas and advanced research projects being conducted, which provide excellent opportunities for innovative businesses, but according to research institutions and enterprises alike, inadequate financing is hampering the development of biotechnology.

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1. Ernst & Young, Back on Track: The European Perspective.
2. Ibid.
3. Ibid
4. Ibid
5. Ibid
The most prominent Polish scientists specializing in biotechnology are:
- Prof. Andrzej ANIOL, specialization: agritech, physiology, genetics and plant breeding – Plant Breeding and Acclimatization Institute, Radzików
- Prof. Włodzimierz BEDNARSKI, specialization: food biotechnology – Academy of Technology and Agriculture, Olsztyn
- Prof. Stanisław BIELECKI, specialization: technical biochemistry, biotechnology, enzymology – Łódź University of Technology
- Dr. Piotr BOROWICZ, specialization: chemistry and technology of antibiotics – Institute of Biotechnology and Antibiotics, Warsaw
- Prof. Józefa CHRZANOWSKA, specialization: food biotechnology and dairy technology – Agricultural University, Wrocław
- Dr. Jerzy CZUBA, specialization: biotechnology, technical microbiology – Institute of Agricultural and Food Biotechnology, Warsaw
- Dr. Jaroslav DASTYCH, specialization: molecular immunology – International Institute of Molecular and Cell Biology, Warsaw
- Prof. Jerzy DUGÓŃSKI, specialization: biotechnology, applied microbiology – Łódź University
- Prof. Adam DUBIN, specialization: protein chemistry, biochemistry, enzymology – Jagiellonian University, Cracow
- Prof. Magdalena FIKUS, specialization: biochemistry, cell biophysics, genetic engineering – PAN Institute of Biochemistry and Biophysics, Warsaw
- Prof. Włodzimierz GRAJEK, specialization: biotechnology, technical microbiology – Agricultural University, Poznań
- Prof. Jacek HENNIG, specialization: biochemistry, molecular biology – PAN Institute of Biochemistry and Biophysics, Warsaw
- Prof. Stanisław LEDAKOWICZ, specialization: bioorganic chemistry, molecular biology – PAN Institute of Biochemistry and Biophysics, Warsaw
- Dr. Jerzy J. LIPA, specialization: biological destruction of agrophages, entomology, integrated plant protection, plant quarantine, protozoology – Institute of Plant Protection, Poznań
- Prof. Jan LUBINSKI, specialization: clinical genetics, pathomorphology – Pomeranian Medical University, Szczecin
- Prof. Sylwia LABUŻEK, specialization: biochemistry, biochemistry of microorganisms, and environmental biotechnology – Silesian University, Katowice
- Prof. Stefan MAŁEPSZY, plant genetics and biotechnology – Warsaw Agricultural University (SGGW), Warsaw
- Prof. Korneliusz MIKSCH, specialization: environmental biotechnology, technology of water, sewage and waste – Silesian University of Technology, Gliwice
- Prof. Jerzy Stanisław NOWAK, specialization: human genetics, immunology – PAN Institute of Human Genetics, Poznań
- Prof. Andrzej OKRUSZEK, specialization: bioorganic chemistry – PAN Centre for Molecular and Macromolecular Studies, Łódź
- Prof. Włodzimierz OSTROWSKI, specialization: biochemistry, protein chemistry, enzymology – Medical College of Jagiellonian University, Cracow
- Prof. Andrzej PLUCIENNICZAK, specialization: biochemistry, molecular biology – Medical University, Łódź
- Prof. Ryszard POHORECKI, specialization: chemical engineering and bioprocess engineering, engineering of chemical reactors – Warsaw University of Technology
- Prof. Antoni POLANOWSKI, specialization: biochemistry, biotechnology – Wrocław University
- Prof. Andrzej RABCZENKO, specialization: biophysics – PAN Institute of Biochemistry and Biophysics, Warsaw
- Prof. Jan J. RYBCZYŃSKI, specialization: plant biotechnology, botany – Botanical Garden, Warsaw Centre for Biological Diversity Conservation, Warsaw
- Prof. Anna SKORUPSKA, specialization: genetics of bacteria – Maria Curie-Skłodowska University, Lublin
- Prof. Zdzisław SMORAG, specialization: animal physiology and biotechnology, animal reproduction – Institute of Zootechnology, Cracow
- Prof. Wojciech J. STEC, specialization: bioorganic chemistry – PAN Centre for Molecular and Macromolecular Studies, Łódź
- Prof. Ewa SYMONIDES, specialization: plant ecology – Ministry of the Environment, Warsaw
- Prof. Krzysztof W. SZEWczyk, specialization: bioprocess engineering, engineering of reactors – Warsaw University of Technology
- Dr. Krystian SZUDYGA, specialization: market gardening – Institute of Market Gardening, Skiernewice
- Prof. Marian TRUSZYŃSKI, specialization: infectious illnesses of animals, veterinary microbiology – National Veterinary Institute, Puławy
- Prof. Tomasz TWARDOWSKI, specialization: molecular biology, biotechnology – PAN Institute of Bioorganic Chemistry, Poznań
- Prof. Stanisław UŁASZEWSKI, specialization: genetics, microbiology, yeast genetics – Wrocław University
- Prof. Halina WĘDRYCHOWICZ, specialization: molecular biology, immunology, parasitology – PAN Institute of Parasitology, Warsaw
- Prof. Kazimierz WIERZCHOWSKI, specialization: molecular biophysics, molecular biology – PAN Institute of Biochemistry and Biophysics, Warsaw
- Prof. Andrzej ZABŻA, specialization: bioorganic chemistry, chemistry of natural products – Wrocław University of Technology
- Prof. Janusz ZIMNY, specialization: plant biotechnology – Plant Breeding and Acclimatization Institute, Radzików
- Prof. Lech ZWIERZCHOWSKI, specialization: biochemistry, molecular biology – PAN Institute of Genetics and Animal Breeding, Jastrzębiec
- Prof. Maciej ŻYLICZ, specialization: biochemistry, molecular biology – PAN International Institute of Molecular and Cell Biology, Warsaw

7. Education and biotech staff in Poland
- Well-educated young people are the engine of Polish biotechnology. There is a high level of education in the natural and engineering sciences in Poland. About 30 universities and institutes across the country offer graduate-level programmes (including Ph.D.) in biotechnology. Among them there are:
  - 3 medical academies,
  - 5 technical universities,
  - 14 universities,
  - 7 agricultural academies,
  - 1 pedagogical academy.
- The total number of biotech students exceeds 5,000 and is expected to keep rising dramatically in the future, by approximately 15% yearly.
- The great potential for dynamic development of Polish biotechnology results from the number of people involved in biotechnology and biomedical research. In 2004 56,775 people were employed in R&D institutes of the Polish Academy of Sciences, other research centres, and R&D units at Polish universities that conduct research in disciplines associated with biotechnology, such as the natural sciences, medical science and agriculture science.
- Much more than 3,000 scientists are involved in biotechnology and biomedical research in Poland. Their research results constitute a large, still-untapped potential with many important solutions waiting for entrepreneurs to commercialize.

8. Organization of research in the field of biotechnology
A three-module organizational structure of science exists in Poland, which means that research activities are conducted by institutions belonging to one of the three bodies:
- The Polish Academy of Sciences (PAN),
- higher education institutions,
- research and development institutes.
This organizational structure may also be considered to apply to research in the field of biotechnology, but it should be stressed that there are no private, independent R&D institutes in Poland in
this field. All R&D institutes in this field are affiliated with higher education institutions, such as universities, technical universities and medical universities. As far as the scientific and R&D units of the Polish Academy of Sciences are concerned, there are several operating in the field of biotechnology (for example the Institute of Plant Genetics, the Institute of Genetics and Animal Breeding, and the High-Pressure Research Centre). On the other hand companies operating in the biotech sector often have their own internal R&D units whose research results are implemented in those companies. Many Polish universities are involved in international cooperation in the field of biotechnology. Examples include:

- Medical University in Bydgoszcz
- Poznań University and the Agricultural University in Poznań
- Wrocław University, Wrocław Technical University and Agricultural University in Wrocław
- Gdańsk Technical University
- Łódź Technical University
- Warsaw Technical University
- Jagiellonian University in Cracow
- Toruń University
- Szczecin University.

These universities are among the most important Polish biotechnology centres.

9. Biotechnology research financing

Research and development in the field of biotechnology in Poland is performed on a high level. In comparison with the US and Western Europe, however, very little funds are available for biotechnological R&D. Some of the sources of biotechnology research financing in Poland include:

- financing from the state budget in the form of various subsides,
- financing from the 6th Framework Programme (from 2007, the 7th Framework Programme),
- financing from European Structural Funds (support under the Sectoral Operational Programme “Improvement of the Competitiveness of Enterprises, 2004-2006”),
- financing of specially commissioned projects. PLN 201,323,000 was provided under the Polish Budget Act in 2005 for R&D projects in the field of natural sciences (biotechnology included). An additional PLN 2,105,466,000 was allocated for the charter tasks and investment policy of the higher education and research institutions. PLN 2,400,000 was provided in subsidies for international scientific and technological cooperation.

10. Participation of Polish research teams in the 6th Framework Programme

- Two competitions of the 6th Framework Programme undertaken under the theme “Health & Life Science” took place in 2005: the 6th competition (FP6-2005-LIFESCIHEALTH-6) and the 7th competition (FP6-2005-LIFESCIHEALTH-7).
- 58 Polish research teams took part in the 6th competition. The total budget of this competition was EUR 381.6 million. Twelve projects, with 16 Polish teams as participants, qualified for financing and negotiation, with the Polish “success rate” of 27.5%.
- There were 44 Polish research teams in the 7th competition. Two projects with 5 Polish partners qualified for financing and negotiation, which gives a “success rate” of 11.0%.
- 407 Polish research teams received funding in the field of biological/medical sciences under the 6th Framework Programme, an increase of 86 teams since the 5th Framework Programme.

11. Legal regulations

- For the last few years Polish legislation has been undergoing significant changes to conform to the European Union model. As a consequence, Polish regulations on biotechnology are based mainly on EU directives or are tied to other international standards.

- On 1 January 2002, the Act on Genetically Modified Organisms (GMO) was introduced. It allows contained use of GMO’s, and release of GMO’s into the environment under certain conditions. The current Act on GMO’s is likely to be replaced. A new GMO bill has been negotiated within Polish ministries in 2006. Under the bill:
- introduction of GMO’s onto the Polish market would require proof that the product is harmless to human health and the environment,
- an effective and comprehensive inspection system would be put in place,
- mass cultivation of genetically modified plants would be banned, and in some special zones, cultivation of GMO’s would require the approval of local authorities.

12. Profile of Polish biotechnology market

- The Polish biotechnology market may be divided into:
- biotechnology in pharmaceutical production,
- molecular diagnostics in medicine,
- food biotechnology (results of which are used for example in production of food products with amino acids and vitamins; include biocatalysis, pre-biotics, probiotics and the like),
- plant biotechnology (viruses-resistant potatoes and strawberries, and plum, tomato and lettuce crops resistant to herbicides),
- animal biotechnology (transgenic animals),
- biotechnology in environmental protection.

- The bio-pharmaceutical sector (red biotechnology) is the best-developed branch of Polish biotechnology, but its growth is expected to be rather stable compared to the dynamically growing sector of agricultural biotechnology (green biotechnology). According to a BioCon Valley report, about 100 out of its approximately 1,000 graduated biotechnologists have specialized in agrobiotechnology, which reflects a great potential for this biotech segment.

- Many companies in Poland specialize in the field of biotechnological environmental engineering. The market leader is Trigger, a company that produces bio-compounds and offers services related to biotechnology and environmental protection.

- Research in molecular diagnostics in Poland is well developed. Examples of successful projects in this field include polymerase (the Polgen company), restriction enzymes (the EURx company), primers for PCR (PAN Institute of Biophysics and Biochemistry), and tests for detecting predispositions to various types of cancer (Szczecin).
13. Regulatory agencies, scope of authority and inspection of GMO’s

<table>
<thead>
<tr>
<th>Area of regulation</th>
<th>Regulatory agencies</th>
<th>Scope of authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commencing any operation involving contained use of GMO’s or intentional release of GMO’s, including introducing GMO products onto the market, requires an assessment of the hazard to health and the environment.</td>
<td>Environment minister, in consultation with the health minister, agriculture minister and science minister</td>
<td>Issuance of a decree specifying how the assessment must be conducted</td>
</tr>
</tbody>
</table>
| Issuance of consents | Environment minister | • Consent to intentional release of GMO’s  
• Consents to contained use of GMO’s |
| Issuance of permits | Environment minister | • Permits to place GMO products on the market  
• Permits for export or transit of GMO products |
| Coordination role | Environment minister | • Coordination of regulatory and monitoring activities covered by the GMO Act  
• Coordination of collection and exchange of information related to health and environmental safety of GMO’s |
| Performing inspections | Sanitary Inspectorate, Plant Protection Inspectorate, Environmental Protection Inspectorate, Veterinary Inspectorate, Trade Inspectorate, State Labour Inspectorate, Inspectorate for Agricultural Product Purchase and Processing, and customs authorities with respect to inspecting legal market turnover in GMO’s | These agencies perform inspections within their area of expertise upon motion of the environment minister. |

Source: Act of 22 June 2001 on Genetically Modified Organisms

14. Genetic modification

• According to the Polish Act of 22 June 2001 on Genetically Modified Organisms, a “genetically modified organism” is a non-human organism in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination.

• Poland currently does not produce or import any genetically modified crops nor are any under development. Additionally, in March 2005, the Polish government implemented a two-year moratorium on the trade and planting of MON 810 maize. There are many further obstacles in Poland to production of GMO’s. However a few permits for field and laboratory research have been issued.

• The International Coalition to Protect the Polish Countryside (ICPPC) has been running the campaign “Stop GMO’s in Poland – Create GMO-Free Zones” since June 2004. The first province was declared a GMO-free zone in September 2004, the last on 16 February 2006. All declarations demanding the right of provinces to create GMO-free zones were signed by province authorities and sent to the national government.

• There are now 16 GMO-free regions in Poland and more than 300 farms from different parts of Poland declared GMO-free zones. In fact, the entire Polish territory (its 16 provinces) is a GMO-free zone.

• The map presents particular communes and counties that have declared themselves GMO-free zones. All national parks are GMO-free zones under Article 23a of the Environmental Protection Act of 16 October 1991.

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7 http://www.icppc.pl/pl/gmo/eng_index.php
• In March 2006 the Polish government declared that it is opposed to the development of genetically modified crops in Poland, but is in favour of importing GM produce into the country. This action puts Poland on a collision course with the European Commission, which has consistently refused to accept national and regional independent bans on GMO’s.

15. Intellectual property protection

• Intellectual property rights in Poland are fully compatible with those of the European Union. The “new” Polish patent law includes modified regulations concerning the patentability of biotechnological inventions. The amendments to the Industrial Property Law harmonize Polish patent law with the EU Directive.

• Patents may hamper the development of domestic technology in Poland, because intellectual property rights are often little known in academia.

16. Patents – statistics

• In 2004 there were 200 patent applications submitted in the field of biotechnology.

• 72 patents in biotechnology were approved in 2002, of which 7 were based on Polish discoveries.

17. Research and development biotechnology centres

• The development of Polish biotechnology is driven by many science centres. They operate as technology parks, technology transfer centres, technology incubators and other research institutes. The main biotechnology research centres are located in the largest cities with a strong academic presence, such as Warsaw, Cracow, Łódź, Wrocław, Poznań, Gdańsk and Szczecin. Some of the centres are science-oriented, affiliated with many non-business organizations such as universities, scientific institutes and R&D centres, while the business-oriented ones are hosted mostly by commercial entities dealing with biotech.

• There are five main Technology Transfer Centres in Poland that deal with biotechnology: in Warsaw, Cracow (the Centre for Innovation, Technology Transfer and University Development at Jagiellonian University), Łódź (established by the Incubator Foundation), Wrocław (Wrocław Centre for Technology Transfer), Poznań and Gdańsk. Technology transfer centres, which are usually created at higher education institutions, choose research results that can be implemented in industry, look for industry partners, train students and scientists in subjects related to commercial application of research results, and so on. They also collect information about different sources of financing. A significant number of innovation and technology transfer centres are members of the Polish Association of Business and Innovation Centres (SOOIPP).

• Technology parks also play a very important role in the development of Polish biotechnology. They offer favourable investment condi-

tions and especially well-developed infrastructure: land, buildings, and telecommunication and transport networks. They also facilitate relationships between business and scientific units and usually have strong support from local authorities.

• Biotech-oriented research groups are also active in business incubators. Business incubators support small and medium-sized companies by providing consulting and training, leasing of technical equipment and office space, creating a favourable climate for cooperation, and the like. They usually operate at higher education institutions or municipal authorities that are responsible for regional development.

18. Centres of Excellence and Centres for Advanced Technologies in the biotechnology sector

Centres of Excellence are units or organizational structures involved in scientific research and the development of high technology at a world level in terms of measurable scientific effects (including training activity). They have a relatively high degree of autonomy and are established by several institutions that operate under a single scientific and organizational management. The research conducted by teams of scientists in Centres of Excellence concern strategic problems of national economies.

Centres of Excellence and Centres of Competence are institutes that present a good example of the Polish research landscape, representing:

• universities and other higher education institutions,
• institutes of the Polish Academy of Sciences, branches of R&D institutions.

The activity of Centres of Excellence may be focused on:

• research in a specific field (university departments, institutes),
• broad interdisciplinary cooperation,
• research based on specific research infrastructure (e.g. CERN),
• cooperation between universities and industry (e.g. Fraunhofer-Gesellschaft institutes),
• development of industrial R&D implementation (e.g. Philips Research Laboratories in Eindhoven).

The existing Centres of Excellence and Centres of Competence in Poland were appointed in the following calls for proposals under the 5th Framework Programme of the European Union and the PHARE programme:

• INCO-2 (1999) - 9 Centres of Excellence,
• PHARE SCI-TECH II (1999) - 5 Centres of Excellence,
• NAS-2 (2001) - 138 Centres of Competence and Centres of Excellence which have received 3.4 or more points out of 5.0 points in the evaluation process,
• IST-2002-B.1.6 (2002) - 5 Centres of Competence and Centres of Excellence which have received 3.4 or more points out of 5.0 points in the evaluation process.

These centres were approved by the science minister.

8 BioCon Valley, Life Science and Biotechnology in Poland

9 http://www.6pr.pl/centra_dosk/index.html

THE BIOTECHNOLOGY SECTOR IN POLAND 5
19. Competition for biotechnology projects

- The last competition of the 6th Framework Programme on the thematic priority “Health & Life Science” has closed. Applicants could make their project proposals by 9 October 2005.
- However, scientific institutions may enter petitions that are announced by the Ministry of Science and Higher Education. Many of the competitions concern biotechnology. Projects that are approved by the Ministry of Science and Higher Education receive a special subsidy from the state budget.

20. Examples of current biotechnology research projects

<table>
<thead>
<tr>
<th>CENTRES OF EXCELLENCE IN THE FIELD OF BIOTECHNOLOGY IN POLAND</th>
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</thead>
<tbody>
<tr>
<td><strong>Name of Centre</strong></td>
</tr>
<tr>
<td>ANIMBIOGEN</td>
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<tr>
<td>BIER</td>
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<tr>
<td>BioMoBiL</td>
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<tr>
<td>CEMBM</td>
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<tr>
<td>DEMETER</td>
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<tr>
<td>EMBEU</td>
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<tr>
<td>PAGEN</td>
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<tr>
<td>PRENABIO</td>
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<tr>
<td>BIO-GENE</td>
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<tr>
<td>SUPERB</td>
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</tbody>
</table>

Source: National Contact Point for Research Programmes of the European Union, website

21. National research institutions on the biotech market

- The majority of Polish national institutions on the biotech market are affiliated with Polish universities.
- The Polish Academy of Sciences (PAN) is one of the most important Polish scientific institutions also in the field of biotechnology. PAN includes numerous institutes, research centres and committees.
- Among the leading scientific institutions in the field of biotechnology in Poland are the Institute of Biotechnology, Warsaw; National Institute of Hygiene, Warsaw; Warsaw Medical University; Institute of Immunotherapy and Experimental Medicine, Wrocław; Wrocław University; Institute of Bioorganic Chemistry, Poznań, Poznań Medical University; Łódź Medical University; Microbiological and Viriological Research Centre, Łódź, Gdańsk Medical University.

22. Private entities on the biotech market

- There is no official definition of a biotechnology firm in Poland. The number of such firms was estimated on the basis of a biotechnology firm survey for reference year 2004, conducted in 2005 by the Ministry of Science and Higher Education.
- In 2004, there were 13 biotechnology firms in Poland. Five firms were classified in the health area, three in environment, two in agriculture and food processing, and bioinformatics and industrial biotechnology had one firm each.

<table>
<thead>
<tr>
<th>BIOTECHNOLOGY FIRMS IN POLAND BY APPLICATION FIELD, 2004</th>
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</thead>
<tbody>
<tr>
<td><strong>Nature of Project</strong></td>
</tr>
<tr>
<td>Fluorescent Cell Chip (FCC) research on detection of substances in the immune system</td>
</tr>
<tr>
<td>Production of biological preparations for destroying listeria monocytogenes bacteria</td>
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<tr>
<td>Enzyme engineering (concerning aspergillus niger IBT – 90) for textile industry</td>
</tr>
<tr>
<td>Production of dressing materials from bacterial cellulose technology</td>
</tr>
<tr>
<td>Research on disease vaccines</td>
</tr>
<tr>
<td>Research on quality control methods for in vitro reproduction of some flowers</td>
</tr>
<tr>
<td>Research on bacterial infections</td>
</tr>
</tbody>
</table>

Source: Based on Information Processing Centre (OPI) data

**BIOTECHNOLOGY RESEARCH PROJECTS CURRENTLY BEING CONDUCTED**

- Source: Compiled on the basis of data from OECD Biotechnology Statistics - 2006
• The largest companies in the field of biotechnology and biomedicine in Poland are Polfa Tarchomin SA (Warsaw), Polpharma SA (Starogard Gdański) and Jelfa SA (Jelenia Góra).
• In 2004, biotechnology firms spent USD 8.7 million on biotechnology R&D, 54% of which was spent on biotechnology R&D and 36% on biotechnology capital (instruments, equipment, land and buildings).
• Some firms were active in the Polish Technological Platform for Biotechnology. They include, for example, Bayer CropScience (Warsaw), BIOTON SA (Warsaw), BTL Sp. z o.o. (Łódź), DSM Food Specialties Poland Sp. z o.o. (Warsaw), DSM Nutritional Products Sp. z o.o. (Mszczonów), EURx Sp. z o.o. (Gdańsk), Laboratorium Kosmetyczne Dr Irena Eris SA (Piaśczyna), MONSANTO Polska Polfarmex SA (Kutno), Przedsiębiorstwo Przemysłu Fermentacyjnego AKWAWIT SA (Leszno), Zakład Farmaceutyczne POLPHARMA SA (Starogard Gdański) and Zakład Przemysłu Owocowo-Warzywnego „Pektowin”, Sp. z o.o. (Jasło).
• Some biotech companies in Poland are set up by foreign investors as subsidiaries. These are mainly in the pharmaceutical and cosmetics industry, for example Merck Sp. z o.o. (Warsaw), FORCHEM (Warsaw), Sederma, C.K.B. Good Clinical Practice Polska (Grudziądz), INFORM Polska (Warsaw) and MDS Pharma Services Poland (Cracow).

23. Largest foreign investors on the biotech market

The largest foreign investors in the biotechnology sector are presented in the table below.

<table>
<thead>
<tr>
<th>Investor name</th>
<th>Country of origin</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baxter Healthcare Corporation</td>
<td>Netherlands</td>
<td>Manufacture of pharmaceuticals, medicinal chemicals and botanical products</td>
</tr>
<tr>
<td>Bayer AG</td>
<td>Germany</td>
<td>Manufacture of chemicals and chemical products</td>
</tr>
<tr>
<td>Biofarma</td>
<td>France</td>
<td>Manufacture of pharmaceuticals, medicinal chemicals and botanical products</td>
</tr>
<tr>
<td>DiverseyLever Holdings BV</td>
<td>Netherlands</td>
<td>Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations</td>
</tr>
<tr>
<td>East Sprins International NV</td>
<td>France</td>
<td>Manufacture of beverages; Human health activities</td>
</tr>
<tr>
<td>Eli Lilly Nederland</td>
<td>Netherlands</td>
<td>Wholesale of household goods</td>
</tr>
<tr>
<td>Fatto SpA</td>
<td>Italy</td>
<td>Manufacture of pharmaceuticals, medicinal chemicals and botanical products</td>
</tr>
<tr>
<td>Glaxo SmithKline</td>
<td>United Kingdom</td>
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</tr>
<tr>
<td>Hexal AG</td>
<td>Germany</td>
<td>Manufacture of pharmaceuticals, medicinal chemicals and botanical products</td>
</tr>
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<td>ICN Switzerland AG</td>
<td>Switzerland</td>
<td>Manufacture of pharmaceuticals, medicinal chemicals and botanical products</td>
</tr>
<tr>
<td>IVAX Corporation</td>
<td>USA</td>
<td>Manufacture of pharmaceuticals, medicinal chemicals and botanical products</td>
</tr>
<tr>
<td>KRKA</td>
<td>Slovenia</td>
<td>Manufacture of pharmaceuticals, medicinal chemicals and botanical products</td>
</tr>
<tr>
<td>Lek d.d.</td>
<td>Slovenia</td>
<td>Manufacture of pharmaceuticals, medicinal chemicals and botanical products</td>
</tr>
<tr>
<td>Novartis AG</td>
<td>Switzerland</td>
<td>Wholesale of household goods</td>
</tr>
<tr>
<td>Sanofi-Synthelabo SA</td>
<td>France</td>
<td>Manufacture of pharmaceuticals, medicinal chemicals and botanical products</td>
</tr>
<tr>
<td>Schwarz Pharma AG</td>
<td>Germany</td>
<td>Manufacture of pharmaceuticals, medicinal chemicals and botanical products</td>
</tr>
<tr>
<td>Spectra</td>
<td>Multinational</td>
<td>Manufacture of pharmaceuticals, medicinal chemicals and botanical products</td>
</tr>
</tbody>
</table>

Source: PAKIZ, 2005

24. Prospects for development of biotechnology in Poland

The directions of biotechnology development in Poland are diverse, depending on the segment of biotechnology. This is why it is difficult to draw common conclusions or to rank research directions within biotechnology as a whole.

• Molecular diagnostics: here it is possible for Polish biotechnology to achieve the highest world standards in molecular diagnostics with relatively low additional outlay. One of the possible ways for Polish biotechnology to grow is to focus on designing molecular tests for detecting predispositions for certain diseases as well as reactions to drugs.
• Because agriculture is an important part of the Polish economy, there is the potential – and the need – to carry out research in agro-biotechnology.
• It is predicted that Polish scientists will continue research on modern biotechnological medicines. Research and development in this field are within the reach of Polish R&D.
• As far as industrial biotechnology is concerned, Polish researchers should be expected to concentrate on novel enzymes and microorganisms, microbial genomics and bioinformatics, metabolic engineering and modelling, biocatalyst function and optimization, biocatalytic process design, and bioprocess isolation and purification.
• Taking into account the existing infrastructure, available raw materials and research, a focus on the following directions of biotechnology development in Poland in the nearest future should be emphasized: biocatalysts, biofuels (bioethanol from starch and lignocellulose, biodiesel), biomaterials/biopolymers, biopharmaceuticals and bioprocesses in environmental protection.
• It should be stressed that rapid growth of the biotechnology sector in Poland requires foreign direct investment. Innovative companies operating internationally may use the great potential of the Polish biotech sector for their own development. The general investment climate in Poland is one of the factors enhancing biotechnology investment opportunities.
• Venture capital funds play a very important role in financing high-tech enterprises, including biotechnology. Venture capital funds in Poland have started operating fairly recently, and the market is far from being saturated. Therefore, taking into account the strong development potential of Polish biotechnology, foreign VC funds can find attractive investment opportunities in this industry.
• The number of graduates of biotechnology faculties at Polish universities is still increasing, which means there is ready access to well-educated staff.
• The knowledge and expertise of Polish scientists meet Western standards. A vast majority of young scientific staff are also highly entrepreneurial and strongly motivated.
• Polish researchers participate in many international initiatives, facilitating the transfer of biotech knowledge.

11 ibid.