 STATUS OF THE POLISH BIOTECHNOLOGY SECTOR

(Financial data in €)

| 52 | Total Biotech Companies |
| 5  | Biotech-Therapeutic     |
| 33 | Biotech-Services        |
| 14 | Biotech-Other           |
| ≥4000 | Employees               |
| ≥200 | R&D employees           |
| ≥0.25m | R&D spending*          |
| ≥130m | Revenue*                |
| ≥5m  | Equity Raised*          |
| NA   | Government grants       |
| 83%  | Percentage of SMEs      |
| 0    | Percentage of companies publicly owned |

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

With 52 companies, Poland has one of the highest numbers of biotechnology companies among the new Member States. Poland has established itself as an attractive location for outsourcing in Europe, and as a result over a quarter of Polish biotechnology companies are contract research and manufacturing companies.

Biotechnology Companies in Poland
Breakdown by Subcategory based on 67 entries by 52 companies

The biotechnology industry in Poland employs over 4000 people and consists 83% of SMEs employing less than 250 people. Approximately one third of these SMEs can further be considered micro enterprises as they employ less than 10 people.
The majority of Polish biotechnology companies were independently founded since 1999 with a recent surge in activity over the past decade.

**POLAND – AN INDUSTRY OVERVIEW**

Poland’s experience in biotechnology goes back as far as 1862 when the Polytechnic Institute of Agriculture and Forestry in Pulawy was established to research plant breeding.

There is a Polish Biotechnology Platform which is a national organisation with the intent of facilitating growth and commercialization of scientific research. The Polish Federation of Biotechnology was also established in 2003 to promote networking with international organizations such as the European Federation of Biotechnology (EFB) and encourage collaboration between academia and industry.

There is a developed pharmaceutical sector in Poland focused largely on manufacturing generic drugs.
Political and Economic Environment

The government supports new technologies, among them biotechnology, that strengthen industry and promote a knowledge based economy. Poland participates in the EU Innovative Economy Operational Programme of 2007-2013, using the funds to focus on R&D of novel technologies and infrastructure. In March 2008 the Polish government adopted an action plan for the development of biotechnology.

Most R&D funding comes from the government; however, preparing grant applications is time-consuming and costly due to the overload of administrative requirements leading some companies to employ full time staff purely for the purpose of filing applications. Furthermore, EU funding is administered on a delayed payment principle preventing some companies with insufficient funds from participating, particularly those at the early stages of development.

Availability of R&D funding in Poland is directly proportional to the phase of the project being supported; hence the more advanced the phase the more funding options available.

Early stage financing is largely derived from public funds such as grants from the Ministry of Science and Information Technology. Funding at this level is modest and the 7th EU Framework programme is the largest European level contributor.

Later stages of R&D are more commonly financed by Polish financial institutions such as Venture Capital funds, banks, and Angel investors. One of these sources of funding is the Regional Network for Equity Investors (RESIK); a project financed by the European Social Fund and the Polish government to bring together entrepreneurs and private investors. Financing at this stage is still difficult to find in Poland but is more visible than in the other new Member States.

Investors in Poland are aware of biotechnology projects but are rarely interested in early stage companies as they do not consistently generate the profits they expect and the timelines to realization are too long. Foreign VCs often require a local investor to be involved in the project making it more complicated to obtain private funds. There are some VCs specialized in IT and one fund focusing on the life sciences (MCI Bioventures) present in Poland.

Support Infrastructure

Most research takes place at the universities, academies and institutes in the cities of Krakow, Gdansk, Lodz, Poznan, Warszawa and Wroclaw.

There are several life science clusters in Poland such as the one established in Krakow in 2007. There are also approximately 30 science and technology parks operating or planned in Poland, at least 10 of which are fully operational and provide premises and support to companies. Furthermore, numerous centres of excellence throughout Poland.

There is, however, no single contact point for information about funding and other business related advice making it difficult for new companies to obtain information. Some consultancies offer these services but they are expensive and their effectiveness has yet to be evaluated.
The workforce
Over 20 universities, academies and medical academies in Poland have departments dedicated to biotechnology. Universities are not greatly oriented towards the needs of industry and communication between the two is limited. Each year approximately 2200 students undertake studies in biotechnology with about 1700 successfully graduating. Students have good theoretical knowledge but exit the existing school system with a lack of relevant industry experience. Often students wishing to gain more experience leave the country to study and work abroad.

Wages in Poland are low and there is a high level of education among the population.

Technology and intellectual property
There are numerous technology transfer offices in Poland but despite this, the technology transfer system is at its developmental stage and will take several years to mature.

There is still no clear regulation of IP rights at the universities in Poland. Therefore researchers are uncertain if they would benefit from any commercialization of their research. Most universities still retain the rights to all conducted research before and after patenting, dramatically discouraging researchers from starting their own small start ups or spin-offs. This situation is slowly beginning to change with Jagiellonski University in Krakow being the first to implement two main regulations defining intellectual property rights as well as conditions for spin-offs. Under these new regulations, profits from spin off companies will no longer legally belong to the university but will be split 50/50 with scientists. Such regulation changes are considered crucial to the propagation of technology transfer and commercialization. There is a Centre of Innovative Technology Transfer and Development for Universities (CITTRU) that advises and coordinates such policy creation.

Patenting in Poland is prohibitively costly as researchers need to use their own limited grant money for patent applications. As a result, Polish scientists focus largely on publishing their findings to obtain further grants and refrain from patenting their innovations. With this in mind the Polish government created the Patent Plus programme in 2007 to increase awareness of IP rights and patenting and ultimately facilitate technology transfer.

There are currently approximately 130 various advisory and patent companies in Poland that can give advice on patent issues as well as the Centres of Patent Information and the Patent Office of Poland.

GMOs are strictly regulated in Poland and stem cell research on embryonic cells is completely forbidden and not supported by the government or the largely religious public in Poland.

The rate of publication and citation in Poland, as in all new Member States, is below the EU average.
### Products in the Pipeline:

The Polish therapeutic pipeline consists of few early stage projects for which only minimal information could be obtained from the companies.

### DEVELOPMENT CAPACITY INDEX

The development capacity index was calculated for Poland according to the description in Appendix A and can be used to compare the status of the Polish biotechnology sector with that of the other new Member States and candidate countries. It consists of a qualitative factor of 56 and a quantitative factor of 295.

### KEY FEATURES

#### 3 positive key features:
- The biotechnology industry is well developed with a high number of biotechnology companies and adequate infrastructure
- The government demonstrated support for biotechnology with the 2008 action plan for biotechnology
- Funding possibilities are visible

#### 3 negative key features:
- Investment in biotechnology products in the seed stage is limited
- Some research such as that concerning stem cells is restricted due to unfavourable public opinion
- Patenting costs are prohibitive for many researchers and companies

While the overall environment for biotechnology in Poland is positive, focus should be given to providing financing options for early stage research.

### SOURCES

The Polish Biotechnology Database (www.polishbiotech.com) part of the global Biotechgate database (www.biotechgate.com)

Survey from the Wroclawskie Research Centre EIT; 2008
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In collaboration with:
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.
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.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biotechnology therapeutics company</td>
<td>5</td>
</tr>
<tr>
<td>Biotechnology services company</td>
<td>1</td>
</tr>
<tr>
<td>Other biotechnology company</td>
<td>3</td>
</tr>
<tr>
<td>&lt; 10 employees</td>
<td>5</td>
</tr>
<tr>
<td>10-100 employees</td>
<td>4</td>
</tr>
<tr>
<td>100-500 employees</td>
<td>3</td>
</tr>
<tr>
<td>500-1000 employees</td>
<td>2</td>
</tr>
<tr>
<td>&gt; 1000 employees</td>
<td>1</td>
</tr>
<tr>
<td>no data or 1 product in development</td>
<td>1</td>
</tr>
<tr>
<td>2 products in development</td>
<td>2</td>
</tr>
<tr>
<td>3 products development</td>
<td>3</td>
</tr>
<tr>
<td>4 products development</td>
<td>4</td>
</tr>
<tr>
<td>5 or more products development</td>
<td>5</td>
</tr>
<tr>
<td>1-2 products on the market</td>
<td>0.25</td>
</tr>
<tr>
<td>3-5 products on the market</td>
<td>0.5</td>
</tr>
<tr>
<td>5-10 products on the market</td>
<td>0.75</td>
</tr>
<tr>
<td>10-20 products on the market</td>
<td>1</td>
</tr>
<tr>
<td>more than 20 products on the market</td>
<td>1.25</td>
</tr>
</tbody>
</table>

Points calculated for all companies in the country were then summed to give the total quantitative factor for that country.
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Information about the project can be found at www.14allbio.eu

All company details and data are available on:

Biotechgate
www.biotechgate.com

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