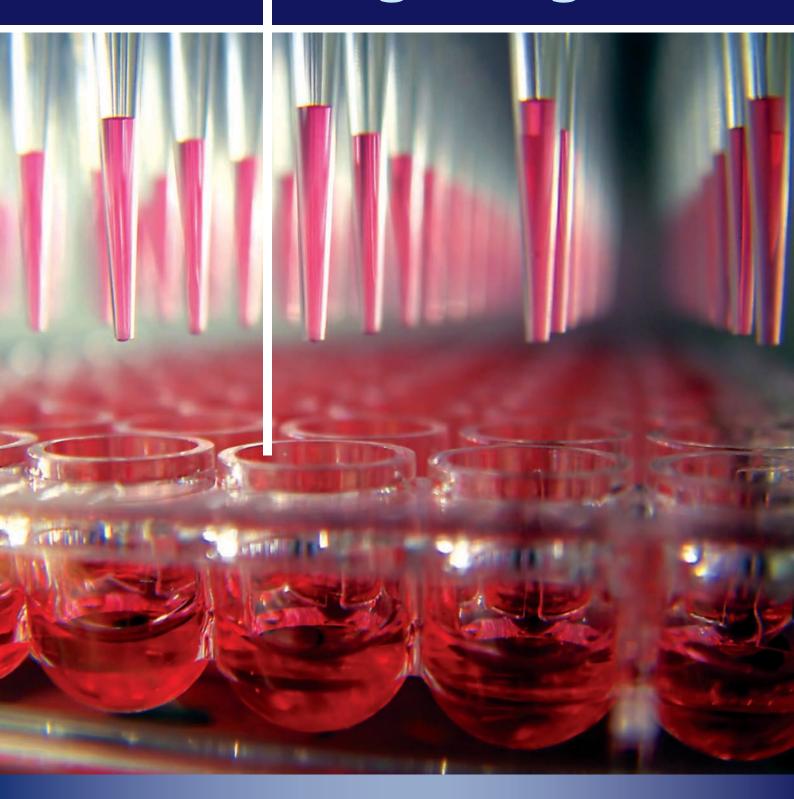




# Life sciences in Hungary: Organic growth



## Under the microscope

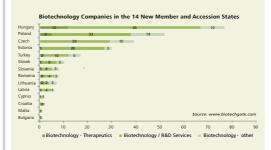
Boasting one of the most developed pharmaceutical and biotechnology sectors in Central and Eastern Europe, Hungary provides an ideal base for life science companies planning further expansion in this region itself, towards the Balkan states, or more distant markets in Eastern Europe and Asia. Investors are supported by renowned research and development services offered by large pharmaceutical companies, a growing number of small and medium-sized biotechnology companies and several fast-growing research institutions. This booklet provides a brief overview of the costs, skills, infrastructure and opportunities in Hungary, as well as a selection of success stories from multinational companies that have already moved key processes to the heart of Europe.

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#### Hungarian biotech: a regional first

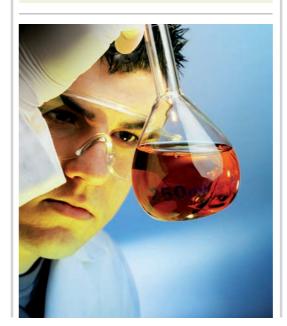
In October, 2009, EuropaBio, the European Association for Bioindustries, and Venture Valuation, with the collaboration of national stakeholders, published a ground-breaking report "Biotech in the new EU Member States: an emerging sector", evaluating the biotech industry across the 12 newest EU Member State, as well as Turkey and Croatia. The report identifies 260 biotechnology companies across 14 countries; and addresses the opportunities and challenges particular to each national situation. Four countries in particular, Hungary, Poland, the Czech Republic, and Estonia, report the highest numbers of biotechnology companies and were the most developed biotechnology sectors among the 14 countries analysed. As for the number of biotech companies, Hungary clearly leads the field.



The Hungarian government has chosen biotechnology as one of its top-five priority sectors in the country's mid-term development plan, but stated that "Hungary... does not want to compete on the basis of low wages and has taken steps to attract back talented Hungarian scientists and managers."



In the survey, Hungary also ranks first in terms of development capacity.



## A breeding ground for innovation

Life sciences are considered a relatively young science in Hungary, with related research areas and industries including animal and plant breeding, but the manufacture of complex chemicals and pharmaceuticals in Hungary is rooted in traditions and internationally renowned achievements.



The national pharmaceutical industry is built on a wide range of accumulated knowledge in chemistry and biology. Hungary is one of the largest and most developed drug markets in Eastern Europe with estimated sales of close to US\$ 3 billion in 2009 and export well over US\$ 2 billion worth of drugs and medical supplies around the world.

Hungarian biotechnology has developed dynamically in the last decade. It is applied not only to technologies using genetically manipulated micro organisms, but in a much wider sense, including the production and application of enzymes and the synthesis of hormones. In Hungary, the main fields of development and application of biotechnology are soils, water pollution treatment, production and processing of biomass, recycling processes, genetic engineering, nanotechnology, molecular chemistry, agriculture and food processing.

More concrete progress has been made in biotechnology applications in industrial production, particularly for medical and paramedical products, including enzymes and intermediaries. In this area, the most important field is the production of factor vaccines. Production of antibiotics is also a significant and traditional area for Hungary. In addition, special attention is being paid to new resistant micro organisms and betalactase derivative antibiotics.

With the active support and commitment of the Hungarian Government, biotechnology now shows dynamic expansion and development. Hungary boasts the strongest biotech sector of the twelve new EU member states. Fifty core biotech companies have been set up in Hungary until now with some 170 companies involved in some form of biotech-related activity. Hungary's major goal is to be recognised as one of the top ten biotech countries in the EU.

During the past few years, more emphasis has been laid on international relations, boosting the export activity of the sector, not only to maintain and improve the position of the industry, but also to attract investors. Hungary contributes to the global biotech industry with vital know-how, world-renowned academic excellence and a long tradition in R&D.

## **Ground-breaking contributions** to life sciences

The first modern pharmaceutical laboratory in Budapest was established by Daniel Wagner in his Nádor Pharmacy. Wagner founded Pest Chemical Factory, later **Hungaria Chemical Works**. As a researcher he worked out various methods to trace arsenic poisoning and also experimented about producing artificial mineral waters.

Hungary's pharmaceutical industry was established by Gedeon Richter (1872–1944), who began industrial-scale manufacture of pharmaceuticals in the laboratory of his Sas ("Eagle") Pharmacy in 1901. The **Gedeon** Richter Pharmaceutical Factory in Kőbánya, Hungary's first pharmaceutical plant, opened in 1907 and has been in operation at the same site ever since. In addition to producing organo-therapic formulas, the factory also dealt with the production of organo-chemical preparations. Several of these products are still being manufactured, including Hyperol, a disinfectant pill or Kalmopyrin a very popular pain-killer and a strong competition to Aspirin (Bayer). The factory was the first to launch large-scale production of the digestive protease: pepsin. By 1932, Richter had more than 32 patented products; operated three branches abroad and 40 representative offices. More than 300 people worked under the control of pharmacists and three chemical engineers. Richter also introduced the production of sulphonamides, synthetic hormones and effective liver preparations.

In 1910, two of Richter's chemical engineers Emil Wolf (1886–1947) and György Kereszty (1885-1937), left the company to establish their own business, the Chinoin Pharmaceutical Factory. By 1918, more than 1000 workers and nearly 100 white-collar employees worked at the factory. Chinoin's new preparations included Sevenal, Troparin, Albroman and Neomagnol, popular drugs even today. Chinoin introduced industrial-scale manufacturing of papaverin.

The Hungarian subsidiary of the Swiss Albert Wander AG, Dr. Wander's Works began operations in the early years of the century, earning international recognition with its leading products: Hordenzym, a breakthrough medicative nutrient for babies and Ovomaltine, which has remained a world-famous brand ever since. After World War II, the company was nationalised and, through a series of mergers, transformed into a large state-owned company **EGIS United** Pharmaceutical and Food Factory.

The **Alkaloida** factory was founded by pharmacist János Kabay (1886–1936) in 1927. In 1925, Kabay discovered how morphine could be extracted from green poppy (Papaver) and tried to exploit this discovery in his new business. The factory developed rapidly and by the early 1930s a large part of the morphine production had been expanded outside Hungary. Kabay, however, could not reap the rewards of his discovery: he died of a rare disease in the age of 39.

**Phylaxia Serums Co**. was established in 1912, and soon became known throughout Europe when it started marketing its sera and vaccines against swine-pest, swine erysipelas, glanders and splenic fever.

#### Hungarian giants of the life sciences



Endre Hőgyes (1847–1906) started medical studies in Budapest and pursued research as professor of physiology at the University of Kolozsvár. Hőgyes made revolutionary discoveries relating to the complex nerve tracks of reflex functions and became

2010.

professor of general physiology and therapeutics of the Budapest University in 1883. In 1890, Hőgyes became head of the Pasteur Institute in Budapest. Hőgyes's dilution vaccination method was adopted and applied with excellent results by other Pasteur Institutes all over the world.



After completing his medical studies at Vienna University in 1900, Róbert Bárány (1876-1936) became a demonstrator at the Vienna Otological Clinic, where he dealt with the physiology and pathology of the human vestibular apparatus.

During World War I, he became a prisoner of war and was transferred to a Russian prison camp. In 1915, Bárány received the medical Nobel Prize. Following the personal intervention of Prince Carl of Sweden, he was released from the prisoner-ofwar camp in 1916, and was presented with the Nobel Prize by the King of Sweden at Stockholm. Life sciences in Hungary.

Béla Issekutz (1886-1979) became professor of the Budapest university in 1937 and he worked here until retirement. His pharmacological research brough outstanding results in several areas including the physiology of the thyroid gland and the action mechanism of the insulin.



Albert Szent-Györgyi (1893-1986) completed his studies in Budapest. In 1947 he left Hungary to settle in the United States and received his PhD from Cambridge in 1927, for his work on isolating what he then called "hexuronic acid" from adrenal

gland tissue. He accepted a position at the University of Szeged in 1931, there, Szent-Györgyi and his research fellow Joseph Svirbely found that "hexuronic acid" was actually Vitamin C (the L-enantiomer of ascorbic acid). They used paprika as the source for their Vitamin C, noting the anti-scorbutic activity of ascorbic acid and discovered that paprika was a rich source of Vitamin C. He later received the Nobel Prize for his outstanding scientific work and discoveries in the field of biological combustion, of Vitamin C and the catalysis of fumaric acid.



Georg von Békésy (1899-1972). One of Békésv's principal contributions was the development of anatomical techniques that allowed rapid, nondestructive dissection of the cochlea in the mammalian hearing organ. In 1947, he went to the Unit-

ed States where he developed a mechanical model of the inner ear with nerve supply. Békésy was awarded the Nobel Prize in Physiology and Medicine in 1961 for his discoveries and research.

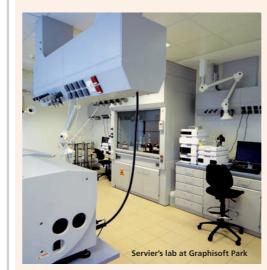
summer 2008, EU ministers chose Budapest t lobalization head on. The organisation is the firs of the "Knowledge Triangle" (higher education research and business innovation) and will seek to stand out as a world class innovation-orientated ref

http://www.eit.europa.eu/

#### **WHY HUNGARY?**

"Hungarian investigators are real partners, not simply executors of protocols carved in stone. They already offer a valuable contribution in the study design phase, which is very much appreciated and extremely helpful." Zsuzsanna Bors, Clinical Research Director // AstraZeneca Hungary

The company founded its clinical research unit in Hungary in 1993, developing it into a regional centre known as the AstraZeneca Clinical Research Region Central and Eastern Europe. It coordinates the work of 160 well-trained Astra7eneca experts located in seven countries of the region. AstraZeneca spends around EUR 6 million on clinical research in Hungary alone, which also covers the work of 1,000 to 1,200 specialists on more than 240 clinical research sites.



"Innovation is key to Servier's competitiveness. It is no coincidence that Servier has decided to reinforce its R&D capacities by establishing its Research Institute of Medicinal Chemistry in Hungary, a country with rich traditions in the pharmaceutical industry, raising some of the finest chemists of the last century. Hungary can be proud of its many Nobel Prize winners and the fact that even today it is a leader in scientific research striving to maintain its position. The new Servier Research Institute fits well into this effort: the skills and expertise of Hungarian chemists further enrich our research programs." Franck Parisot, General Manager of Servier Hungary

## Why Hungary?

#### Business potential: in vivo

Whether you are a producer of biotech products looking for a costeffective manufacturing base, competitive contract research facilities, or locations for logistics and distribution centres, Hungary has plenty to offer.





- Hungary is at the heart of Central Europe, a region characterised by dynamic economic growth driven by high industrial output, excellent export potential and increasing domestic demand.
- Hungary lies along the Eastern border of the EU and is within the Schengen zone. The country's strategic position, highly developed logistics and utilities infrastructure and traditional role as a trading post makes it increasingly important as a regional distribution centre and a natural service hub for the CEE region.
- Four trans-European motorways run through Hungary, more than in any of the neighbouring countries. Most countries in the Balkans can only be reached through Hungary.
- As a member of the European Union, Hungary has fully harmonised its legal system, adopting European safety and quality regulations related to biotechnology. Hungary also compares very favourably when it comes to data security and enforcement of intellectual property rights.
- Highly skilled, creative and flexible human capital at competitive cost.
- Companies can expect a 30–50% cost savings compared toWestern Europe and the US. The average gross wage in Hungary is just EUR 747 per month while labour productivity is among the highest in the CEE region. The Hungarian labour force also rates highly in international comparisons for innovation and creativity, due to the country's renowned schooling and tertiary education system.
- Business processes have been simplified considerably in recent years. In addition, foreign companies willing to settle in Hungary are welcomed with comprehensive trade development services and supportive government policy.
- Some of the world's largest suppliers, including Sanofi-Aventis, Teva, Servier, ICN, Bristol Meyers Squibb, AstraZeneca and GlaxoSmithKline are already present in Hungary. Many have chosen Hungary as location for pharmaceutical supply centres, not only the for CEE markets but also for the Ukraine, Russia and the Balkans.
- Hungary has a globally recognised academic and university infrastructure. Increasingly, biotech-related R&D activity is carried out in top universities and research institutions, while leading global manufacturers, including Sanofi-Avensis, GlaxoSmithKline and Teva, have all established R&D centres in Hungary.

R&D spending

## Legal background

Prior to its accession to the European Union, Hungary had harmonized its regulatory system with that of the EU, including patent, IP, confidentiality protection and privacy. EU membership strengthened the regulatory system to ensure a transparent operating environment.

#### Patent legislation

Protection of intellectual property in Hungary safeguards copyrights and related rights, as well as trademarks, patents, supplementary protection certificates (SPC), plant variety protection, topography protection, industrial designs and utility models.

By law, an invention is patentable if (I) it is new; (II) it is a result of inventor activity; and (iii) it can be applyed in industry. Once an invention is patented, the patentee holds the exclusive right to utilise the patent in question for a period of 20 years. Such utilisation includes the right to (I) manufacture, (II) usage, (III) marketing, and (IV) disposal to third parties of the patented product.

#### **Key legislation**

- Act XXXIII of 1995 on the Protection of Inventions by Patents
- Decree 20/2002 (IM) on formal requirements of patent applications
- Decree 19/2005 (GKM) on fees for industrial property procedures
- Decree No. 147/2007 on rules concerning electronic filing

#### Biotech-related legislation

#### Act on Research and Technological Innovation CXXXIV of 2004:

- Based on the Bayh-Dole Act.
- Promotes the entire innovation process, from the idea to the realization
- Guarantees promotion of IPR utilisation
- Promotes spin-offs and mobility
- Encourages the creation of high value added workplaces
- Fosters improvement of both professional skills and the recognition of researchers performance.

#### Law on Biotechnology Activities (Act XXVII of 1998) Enacting clauses: 1/199 FVM and 44/1999 FVM

Key features:

- Laboratories need accreditation
- Genetic modification is subject to risk analysis
- Genetic engineering is subject to liability rules
- GMO-s and all food containing it should be registered
- Establishment of an advisory body

The Medicines Act (1999) brought national procedures in line with EU directives.

The **Pharma Economic Act** (2007) modified the reimbursement system for pharmaceutical manufacturers.

#### Animal welfare

The Association of Hungarian Pharmaceutical Manufacturers (www.magyosz.org) believes that animal experiments are indispensable for the research of new drugs to reduce human suffering and pain. All members agree to apply the Rule of Three "R's" (replacement, reduction and refinement) to animal protection.

Around 170 thousand animals, mainly rodents, are used for experiments annually. The pharmaceutical industry has remained the largest user of experimental animals in Hungary. Around 70-75% of pharmaceutical research is carried out in vitro. The conditions under which experimental animals are kept in Hungary meet international standards. Animal experiments are carried out in keeping with strict provisions of experimental and ethical code. A local animal experiment board must operate at each company and regular staff training courses are mandatory.

The Association has also set up an Animal Experimentation Ethical Committee with its experts taking part in the work of the national-level Animal Experimentation Ethical Council.

#### Patent management

Hungary files more patent applications and has more patents granted than any country in Central and Eastern Europe. The **Hungarian Patent Office** (www.hpo.hu) was established for the protection of intellectual property in 1896.

In Hungary, a patent may be obtained through national or European patent procedures or via an application submitted in accordance with the international Patent Cooperation Treaty (PCT). The issue of patents is contingent on compliance with the relevant laws and regulations of both the application and the invention itself

Outside Hungary, patents may be obtained by filing an application with the relevant national office or, for Member States of the European Patent Convention (EPC), by submitting an application through the European patent process. Patents are issued following approval procedures carried out by the competent authority.

Other processes in connection with patent protection also fall under the jurisdiction of the Hungarian Patent Office. The Board of Experts on Industrial Property at the Hungarian Patent Office provide consulting services to companies or issue recommendations upon the request of a court on all legal issues in connection with industrial property arising within Hungary.

In the absence of any provisions of an international treaty to the contrary, foreign applicants must be represented by an authorised patent attorney or an attorney-at-law in all patent matters within the competence of the Hungarian Patent Office.

A searchable database of published patent documents is publicly available.

#### Key biotech statistics in Hungary Core biotech companies . 77 Biotech companies 150 **Employees** 900 R&D employees 450 EUR 25.8 million Net sales revenue EUR 18.7 million Export revenue

EUR 4.8 million Investment Source: Convincive Consulting, Hungarian Biotechnological Association, 2009

EUR 10.7 million



#### Quality of research

The World Economic Forum Global Competitiveness Report (2009/2010) surveys company executives and evaluates 133 countries every year. One criterion is the quality of research institutions in which the Forum ranked Hungary 23rd of 133 countries. This puts Hungary ahead of most of its regional competitors, as well as China and the Mediterranean countries.

| Ranking     | Country |
|-------------|---------|
| Switzerland | 1       |
| US          | 2       |
| Germany     | 5       |
| Czech Rep   | 19      |
| Austria     | 21      |
| Hungary     | 23      |
| Slovenia    | 26      |
| China       | 35      |
| Spain       | 44      |
| Poland      | 48      |
| Greece      | 77      |
| Slovakia    | 86      |

## Sector overview **Biodiversity**

- Uniquely for Central and Eastern Europe, Hungary has over 50 biotechnology companies of various sizes focusing their activities wholly or partially on biotech research and development or manufacturing.
- Hungary has a recognised research base in biotechnology and strong collaborative ties to universities and companies in the US, Europe and Japan.
- The majority of core biotech companies was established in the past few years and market their products and services worldwide.

#### Innovative areas in biotechnology

Chemistry and clinical medicine are two major areas where Hungarian researchers have made major achievements in terms of the number of publications (Web of Science, Thomson Scientific). The majority of newly founded companies come from red biotechnology. Hungary also has a strong research base in industrial and green biotechnology as well.

#### **Human biotechnology**

Molecular biology **Biomarkers** Vaccines ADME

#### Industrial biotechnology

Bioremediation Enzyme technologies Inorganic nanostructures Mesoporous materials

#### Green biotechnology

Molecular aspects of plant and animal development Environmental bio-safety Bio-fuels and biogas related research

#### Nanotechnology

Bio/chemical sensors Medical instruments Composite polymers Laser technology Ceramics Metallurgy Thin layer coating and surfaces

#### **Bioinformatics**

Bioinformatics education at Bsc & Msc level at three universities

#### Priority fields of study:

- DNS chip analysis
- Chemoinformatics
- Genome nanotechnology
- Multivariate statistical analysis
- Protein structure prediction
- Scale-free networks
- Individualized medicine
- Single nucleotide
- Polymorphism

- Tracking systems
- Personalized medicine

**Upcoming research areas:** 

#### Medical imaging

Several medical imaging and visualization related courses offered at BsC and MsC levels at three life science universities

#### Priority fields of study:

- Information technology
- Applications in medical imaging
- Surgical planning
- Automatic tumour detection
- 3D CT images

## **Sector overview**The Pharmaceutics

#### **Current situation:**

- One of the largest and most developed drug markets in the Eastern European region, with estimated sales close to US\$3 billion in 2009
- EU accession in 2004 leading to the alignment of Hungary's primary pharmaceuticals legislation with EU standards
- The best track record in the region for FDI in the pharmaceutical sector
- At US\$310, Hungary's per capita spending on drugs is above average for the region (source: BMI, February 2010)
- 10 large universities offering life sciencesrelated tertiary education, with close to 25,000 students, 3,300 graduates and 1,000 PhD students each year.

#### The pharmaceutical market

- Since January 2007, 289 non-prescription drugs may also be sold outside of pharmacies
- The branded products sector will grow in the long run due to increasing health awareness and spending power.
- 47.7% of the market consists of patented products and 39.6% of generics
- BMI forecasts 3.4% growth in local currency terms and 8.9% y-o-y increase in USD terms in 2010
- From 2009-2014, BMI forecasts a CAGR of 3.6% in local currency terms and 3.0% in US dollar terms.
- Over BMI's 10-year forecast period, similar patterns will prevail, with total drug expenditure projected to reach HUF 911.9bn (US\$4.64bn) in 2019, marking a CAGR of 3.4%.

#### Pharmaceutical production

Pharmaceutical production in Hungary increased 2.35 times between 2000 and 2009, while foreign direct investment increased 2.25 times in the sector between 2000 and 2008.



## Largest pharma companies and their main research areas

- **Teva Biogal Pharma** production mainly for export // research areas: neurodegeneration, neuroprotection, autoimmune illnesses, oncology
- Sanofi-Aventis Chinoin production and R&D, development laboratory and prototype factory two molecules from Hungary in the development pipeline priority field of study: inner medicine
- Egis Servier manufacturing and R&D, third largest innovation capacity in the region research areas: oncology, diabetes
- Alkaloida SUN Pharmaceuticals generic pharma manufacturing, planned: development
- Richter Gedeon largest independent drug maker in Eastern Europe, large sales in CIS largest R&D base in Central Eastern Europe research areas: diseases of the central nervous system
- AstraZeneca the company's second largest research base is in Hungary fields of study: vascular diseases, gastroenterology, neurology, oncology
- **GlaxoSmithKline** Hungary is a key location: regional R&D centre, vaccine production
- Kéri Pharmaceuticals Actavis produces and sells generic drugs
- Béres Zrt. market leader in manufacturing and distributing preventive health products; new R&D laboratory.

#### **WHY HUNGARY?**

Since Chinoin's privatisation in 1991, **Sanofi-Aventis** have invested a total of €625 million in its Hungarian subsidiary to increase production, granulation and packaging capacities, and improve environmental technologies. Sanofi-Aventis 's R&D centre for internal medicine in Hungary has been involved in more than 60 development projects since 1996, including initial research and clinical testing. In 2006,Sanofi-Aventis opened an €15 million development laboratory and prototype factory at Chinoin. Sanofi-Aventis employs over 2,500 people in Hungary.



"In general, education is definitely one of the comparative advantages of Hungary in the pharmaceutical industry. ...Hungary is well know for its quality of education, But it is also known, unfortunately, for losing many students abroad. We try to lure HUngarian scientists back to Hungary. ... (Hungary) has a very long tradition in pharmaceutical chemistry; its expertise in this field comprises the core of our activity. The level of creativity is very high."

**Frédéric Ollier**, CEO of Sanofi-Aventis Chinoin in an interview with HINT magazine

## US pharma company opened research centre in Budapest



The Hungarian unit offers early phase drug discovery R&D services and sells "off-the-shelf" small molecule libraries to Western European, US and Hungarian pharmaceutical and biotechnology companies involved in drug discovery and development. AMRI Hungary was founded by the acquisition of the Hungarian company ComGenex in 2006.

#### Chiltern office launched

Global clinical research company Chiltern International opened its new office in Budapest in July 2009. The office will be co-ordinating clinical trials in Hungary. Chiltern expects to receive business primarily from companies operating in the pharmaceutical and biotechnology sectors.

## A gateway for European clinical trials

According to a report of IMS's Biopharmatiques, Hungary is seeking to become a gateway for European clinical trials. The country is currently third in the Central and Eastern European (CEE) states with regard to the numbers of clinical trials conducted (first and second are Poland and the Czech Republic respectively). 320 studies were authorized in Hungary in 2007, with 313 in 2008 and in 2009 (around half being Phase III studies).

The country's oldest contract research organization (CRO), HungaroTrial, is currently studying an increase in capital to extend its activities further in the region, in particular to the Ukraine. It is also seeking to open an office in the US and, with its sister company, ME Trial Masters Ltd, has set up a number of clinical research training courses.

The CEE region offers a number of advantages for companies wishing to conduct clinical trials. There is a high incidence of certain diseases, particularly cardiovascular and pulmonary diseases, and clinical trial participation allows many patients not previously treated to access health care, make rapid patient recruitment easier.

## Sector overview Clinical research

Hungary has a proven track record and global reputation for attracting and conducting international clinical trials, with over 250 clinical trials performed each year an outstanding number considering Hungary's population.

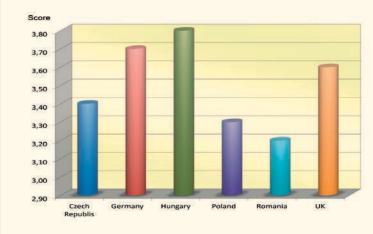
#### Benefits of conducting clinical trials in Hungary:

- Rapid and reliable recruitment of study population
- EU-compliant legislation
- Wide availability of treatment-naïve patient population
- High patient confidence in physicians and Western medicines
- Hungarian investigators' motivation and qualification internationally recognised
- Exceptionally high quality of data
- Excellent English language skills
- Modern hospital equipment to support complex studies
- Centralised health care system: high concentration of patients
- Several well-equipped Phase I study centres
- Qualification of local study monitors and CROs above international average
- Cost benefits: monitoring costs at 60–70% of US prices, investigator and hospital fees below 70% of US levels

In large multinational studies, Hungary is usually 2 to 4 months ahead of the patient recruitment schedule. Many US-based pharmaceutical companies initiate rescue projects in Hungary if patient recruitment of their ongoing studies in US or Western EU countries fail to meet their targets.

#### CRO in selected CEE countries

Buck Consultants benchmarked some countries in 2009, and found that based on labour costs, patent population, labour availability, infrastructure, regulatory framework, business climate and accessibility, Hungary ranked top in Clinical Research. Clinical trial costs in Hungary are 22% lower than in the US, 31% lower than in the UK and 80% lower than in Germany.



Source: Biotech 2010 Life Sciences: Adapting for Success, Burrill & Company 2010

## The Hungarian Government's biotech strategy

Biotechnology has been chosen by the Hungarian government as one of the top five priority sectors in the country's mid-term development plan. The strategy is designed not only to elevate Hungary to be a clear biotechnology leader among the EU accession countries, but also to place it among the top 10 EU states by 2010. To complement the government's mid-term biotechnology strategy adopted in 2005, a new Pharmaceutical and Biotechnology Action Plan was laid down by the Government in July 2009.

While the strategy has remained the same, i.e. to provide a favourable regulatory and development environment in order to increase the competitiveness of pharma and biotech companies in Hungary, the Action Plan has a number of specific objectives including the following:

- To promote the restructuring of the Hungarian pharma industry in line with international trends and based on the strength of the domestic biotech sector;
- To enhance the role of biotechnology in pharmaceutical innovation and to increase the number of international R&D centres founded on domestic knowledae:
- To promote partnership between universities and industry, mobility of human resources and knowledge transfer;
- To enhance the role of the biotech sector by exploring new markets for domestic pharmaceutical research.

#### Investment incentives

Foreign investment promotion through special incentives has always been high on the government's agenda. ITD Hungary, the government's investment and trade development agency offers comprehensive information on currently available subsidies and specifically supports high value-added investment projects with a one-stop shop service including a VIP treatment and special incentives packages.

Investments in the life sciences sectors may benefit, most of all, from incentives supporting research and development.

#### I. Tenders co-financed by the EU:

Start-up of corporate R&D centres

If at least 10 new research and research assistant jobs are created and the investment volume does not exceed EUR 40 million, a non-refundable grant of HUF 200-1500 million can be applied for. See details in box.

#### II. Special incentive package

Investors of certain project groups (manufacturing, tourism, regional service centres, logistics facilities, bioenergy facilities, R&D facilities) under specific conditions may apply for such packages.

#### Results and initiatives

- New initiatives for repatriation of scientists of Hungarian origin
- BioManager Training Programme initiated by the Hungarian Biotech Association
- "Innovation Act", similar to Bayh-Dole Act, passed
- Five biotech-focused regional knowledge centres set up at major universities
- Cooperative Research Centre programme allowing companies to build joint infrastructure at major universities, and join early-stage pre-competitive research
- State-funded and PPP biotechnology incubators set up
- State-funded SBIR-like preseed/ seed financing programme (Irinyi János Programme) initiated - almost half of first winners are biotech projects
- State-funded seed-expansion capital fund set up
- Programme to strengthen natural sciences education • Massive presence of biotech companies at international conferences and US/Asian road-shows with the help of ITD Hungary, the government's invest-
- ment agency • Up-to-date database on biotech sector and biotech investment opportunities
- JEREMIE programme (2009)



#### Start-up of corporate R&D centres (GOP-2009-1.3.2 (KMOP 1.1.5)

Aim: The tender supports the start-up and development of corporate R&D centres and creating R&D employments

**Conditions:** At least 10 new research and research assistant jobs are created

Eligible costs: Tangible assets and personal costs for new employment

Amount of incentive: HUF 200-1500 million, but may not exceed 60% of eligible costs in case of GOP and 25% in case of KMOP

Application: from 31 May 2010 - 10 January 2011 (in case of GOP) from 31 May 2010 - 30 August 2010 (in case of KMOP) at the Hungarian Centre for Economic Development (MAG Zrt) by submitting a tender package.

Further information: http://www.nfu.hu/doc/1765 (in Hungarian only)

#### Cash subsidy for R&D investments

#### **Conditions:**

- The project needs to comply with R&D validation • Investment volume should be at least EUR 10 million
- At least 10 newly created jobs



#### Amount of subsidy:

Criterion

The level of subsidy may vary between 10%-25% of the total eligible investment value.

Scale of subsidy

#### (a percentage of the total investment volume) Base subsidy, all qualified projects 10% may receive In case the company has proven co-operation with a governmental research institute, a non-profit research institute or with a university may be entitled for the following additional subsidy.

In case the company has proven co-operation with a small- and medium-sized company between 10% and 19% of the total eligible costs of the R&D project, may be entitled for the following additional subsidy

In case the company has proven co-operation with a small- and medium-sized company between 20% and 29% of the total eligible costs of the R&D project, may be entitled for the following additional subsidy.

In case the company has proven co-operation with a small- and medium-sized company between 30% and 39% of the total eligible costs of the R&D project, may be entitled for the following additional subsidy.

In case the company has proven co-operation with a small- and medium-sized company between 40% and 49% of the total eligible costs of the R&D project, may be entitled for the following additional subsidy.

4%

In case the company undertakes to maintain the capacity, the basic and newly created workplaces for minimum one year and maximum five years after the close of the R&D project may be entitled for the following additional subsidy per year.

As for research and development (most relevant for the life sciences sector) the incentive package will be applicable in case the investment volume amounts to a minimum of EUR 10 million. The Incentive Package may consist of the following elements:

**Direct subsidy** – decided individually by the Hungarian Government, defined as a percentage of eligible costs (see box).

**Development tax allowance** – For a minimum of HUF 100 million R&D projects. If the investment fulfils the eligibility conditions, 80% of the corporate tax rate (19%) is deductible for a period of 10 years following the completion of the project.

**Training subsidy** – From 25% to 90% (max. EUR 1 million) of eligible training costs (for more than 500 newly created jobs, EUR 2 million), depending on the type of training and location

**Job creation subsidy** – From HUF 0.8 to 1.5 million per job created for investments creating new jobs preferably in disadvantageous regions and to support employment of disadvantaged workers. At least two new full-time positions must be created at the site of the investment project.





#### III. Further tax-related R&D incentives

- R&D costs or depreciation of activated/accounted R&D can be 100% deducted from corporate tax base and solidarity tax base\*
- 10% (in case of small and medium-sized enterprises, 15%) of R&D direct costs and wage costs of the employed software developer can be deducted for a period of 4 years\*
- Tax free employment of PhD, MSc or MBA students (up to the official minimum wage) in the field of educational and research activities\*
- Tax allowance for corporate donations to organisations of public benefit supporting R&D activities\*
- Tax free development reserve for five years, 50% of pre-tax profit (max. HUF 500 million, app. EUR 1.8 million)\*
- Tax benefit on credit agreements is the only type of incentive besides the cash and development tax allowance, which is set by the regional intensity
- 300% R&D direct expenses maximum HUF 50 million (approx. EUR 185 thousand) - if operation of the company R&D unit located at university or public research institute (e.g. Hungarian Academy of Sciences) can be deducted from corporate tax base

\* independent of maximum regional intensity rates

For further details and updates please contact:

Ms. Anita Szucsik, Deputy Director for Incentives & After Care, ITD Hungary Phone: +36-1-473-8269, • E-mail: subsidy@itd.hu

### **Organizations**

#### National Office for Research and Technology

NKTH (www.nkth.gov.hu) plays a key role in elaborating and implementing Hungary's science-, technology- and innovation policies. NKTH provides support for the creation, dissemination and exploitation of new scientific results and technologies, it also promotes the harmonic development of Hungarian national innovation system and fosters Hungarian participation and better representation thereof in international networks of science, technology and innovation. To provide financing for the above activities, the government created the Research and Technology Innovation Fund managed by NKTH.



#### **Hungarian Biotechnology Association**

The HBA (www.hungarianbiotech.org) was established by Hungary's leading life science companies in 2003 as a pioneer among the EU accession countries. The main objective of the organisation is to create an alliance that unites the voices and interests of companies, researchers, academic institutions and related organisations, and to help them in identifying opportunities in the field of life sciences. Through its various national and international projects, the organisation aims to improve and shape the public understanding of biotechnology, promote the safe and ethical use of biotechnological innovations and educate the future generation of biotechnology managers.

HBA represents its members in the most important international biotechnology organizations, such as BIO (The Biotechnology Industry Organisation), EuropaBio (The European Association for Bioindustries) and EFB (The European Federation of Biotechnology). By participating actively in these organisations, HBA also mediates in international dialogue between policy makers and stakeholders on an international level. The organisation also represents its members and the Hungarian biotech sector at major international trade shows, such as BIO, BioSquare, CORDIA and Drug Discovery Technology meetings.

Contact: **Ernő Duda, Jr**., *President, Hungarian Biotechnology Association*Közép fasor 52. 6726 Szeged, Hungary
Phone: +36 62 312 559 • E-mail: info@hungarianbiotech.org
www.hungarianbiotech.org

#### Associations

- Hungarian Pharmaceutical Manufacturers Association www.magyosz.org
- Association of Innovative Pharmaceutical Manufacturers www.igy.hu
- Hungarian Chemical Industry Association
   www.mavesz.hu
- National Association of Health Care Providers

   www.oevosz.hu
- Association of Medical Device Manufacturers

   www.mdma.hu/english
- Association of Manufacturers and Distributors
   Modical Appliances Appliances Appliances
- of Medical Appliances www.amdm.hu
   Hungarian Society for Bioinformatics www.renyi.hu
- Hungarian Association for Innovation www. innovacio.hu
- Hungarian Spin-off Association (HSA)
- www.europeanspinoff.com

#### Selling innovation

In the past couple of years, several Technology Transfer Offices have been established adjacent to life science knowledge clusters to generate and assist with the commercialisation of innovation, promote industrial partnerships and to facilitate the formation of spin-offs.

#### TTOs involved in biotechnology:

Szeged University – www.biopolisz.hu

Miskolc University – www.uni-miskolc.hu/ittc

**Debrecen University** – http://gnd.unideb.hu/gnd

**Budapest Semmelweis University (SOTE)** – www.semmelweisinnovations.com

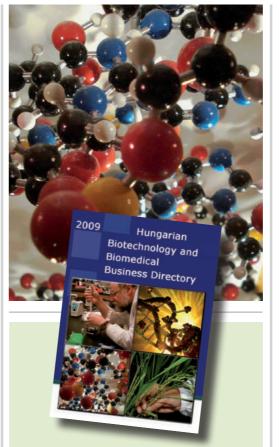
**Pannon University** – http://strategia.uni-pannon.

Pécs University – www.innovacio.pte.hu

#### Safeguarding intellectual property



The **Hungarian Patent Office** (www.hpo.hu) was established in 1896 by the Hungarian government to safeguard intellectual property. The Office has over 110 years' experience of granting patents following search and thorough examination. In addition to its official grant procedure, the HPO also offers an increasing range of business services, including several hundred searches each year for domestic and foreign clients in both traditional and high-tech fields.



For more details about the projects outlined here above, please contact Mr. Tamás Székely Project Manager at tamas.szekely@itd.hu, or Ms. Bernadett Fodor Project Co-ordinator at bernadett.fodor@itd. hu. For additional investment leads, visit http://biotech.itdhungary.com/.



**Klonilla: the first clone mouse in Central Europe** Biotalentum Ltd. and Agricultural Biotechnology Centre, Gödöllő.



The Hungarian teams are leading 8 EU and Welcome Trust funded projects to improve animal models to understand the genetic causes of human diseases. Several clone mice and rabbits were created from somatic cells as a technological breakthrough in the region. Current projects are aimed at the cloning of rats, farm animals and to develop embryonic- and induced pluripotent stem cell technology in mouse and human for regenerative medicine and drug testing.

## Leads from the labs Tips for investors

## DermaVir Patch: Therapeutic vaccine against HIV/AIDS (Drug Delivery & Technology)

DermaVir immune therapy will help control viral replication in HIV infected patients and extend the period before antiretroviral treatment is required. This will improve quality of life and result in fewer side effects while considerably reducing health care costs. The DermaVir Patch therapeutic vaccine is currently in one phase I/II and two phase II clinical trials in the US and EU. All trial reports are expected in Q2 2010. The project is currently in beta and is covered by patents. The project owner is forecasting a return on the total investment of €2,000,000 within 3 years. Potential investors are offered partial ownership in the company.

## Deuterium Depletion in Cancer Treatment and Prevention (Therapeutics)

In vivo deuterium depletion is a new proprietary procedure for the treatment and prevention of various types of cancer. The product is in the manufacturing, distribution and sales phase and is covered by four patents registered in more than 20 countries. The project owner is forecasting a return on the total investment of €2,000,000 within 3 years. Potential investors are offered partial ownership in the company.

## Embryonic Stem Cell Derived Cardiomyocytes for Drug Testing

(Drug Development)

This internationally unmatched test system for the pharma/biotech industry and medical market uses known mouse and human embryonic stem (ES) cell lines to develop innovative methods for the targeted preparation of differentiated cardiac muscle cells. The project is currently a fully developed concept in the R&D phase.

## Omixon Genome Computing Services (Bioinformatics)

The Omixon web portal provides easy-to-use, cost-effective, reliable and secure software and infrastructure for calculations related to gene and genomic sequencing. The project is currently in beta but is in the manufacturing, distribution and sales phase. The project owner expects a return on the total investment of  $\in 3,000,000$  to  $\in 5,000,000$  within 3-7 years (25-70% IRR). The exit value of the company in 5 years is forecast at  $\in 50,000,000$  to  $\in 200,000,000$ , which would require follow-on investment rounds totalling  $\in 10,000,000$  to  $\in 20,000,000$ . The project owner is looking for a joint-venture partner to acquire partial ownership in the company, or an investor looking to boost project capital.

#### Life science clusters

Scientific creativity is one of the most widely acknowledged talents possessed by Hungarians. This is particularly true in the fields of natural, technical and medical sciences. The Hungarian pharmaceutical industry and related sciences of pharmacy, biotechnology and medical equipment technology are steeped in tradition. In the past few years, biotechnological research and medical equipment innovation has been boosted by life sciences knowledge centres offering:

- World-renowned academic and university backgrounds with cutting-edge biosciences competence
- Highly skilled, low-cost scientists and laboratory staff with experience in international working environments and strong collaborative ties with universities and companies in the EU, US and Japan
- Over 25,000 life sciences students in tertiary education and 2,000 in vocational secondary education in academic year 2008/2009
- Large number of highly educated graduates (3,300 with diploma, 1,600 with secondary education)
- Impressive results in basic research







#### Life sciences research and development is centred around four major cities of Hungary:

#### Budapest

- Semmelweis University (SOTE) widely recognized as one of Europe's leading centres of medicine and health sciences combining innovation and tradition in education. 80 departments involved in R&D.
- SOTE, János Szentágothay Centre of Excellence: immuno-genomic research, modified tissue proliferation, info-bionomics in medicine, neuro-scientific research. Manages a Hungarian-Singaporean bioimaging consortium and cooperates with Richter, Hungary's largest pharmaceutical company.
- Highest number of biotech and pharma companies.
- Research projects in the preclinical and clinical departments are supported by Hungarian and international programmes involving 100 higher education institutions abroad.
- Contract research sponsored by pharmaceutical companies is also an important part of scientific activity.
- Cell Communication Knowledge Centre, ELTE: development of new technologies based on research of diseases caused by impaired cell communica-
- Central Hungarian Innovation Centre: ValDeal, an innovation integrator company provides complex services to seed-phase companies, including spin offs.
- Institute of Experimental Medicine, Hungarian Academy of Sciences: pharmacological and neurobiological research and medical gene technology development employing a multidisciplinary approach.

#### Pharmapolis to set up HUF 6bn pharmaceuticals R&D service centre by new Richter plant

Science Park, a HUF 6bn pharmaceuticals research, development and innovation service centre to be set up in Debrecen (E Hungary) by Pharmapolis, partly owned by Richter, will strengthen the professional background for Richter's new plant being built there. Richter started the construction of a HUF 15 billion biotechnology, R&D and manufacturing plant in Debrecen in Q3 2008. The government granted nearly HUF 1.4 billion in support to the investment last year.

Pharmapolis Kft, a company comprising Debrecen Asset Management Zrt, the Regional Chamber of Industry and Commerce, and the pharmaceutical company Richter Gedeon Zrt, will set up Science Park as a greenfield investment on an area of almost 8,000 sgm to attract pharmaceutical SMEs to the neighbourhood of the new Richter plant.

#### Egis awarded HUF 226m grant to support HUF 3.78bn R&D base

Drug maker Egis, majority-owned by France's Servier, was awarded a HUF 226m state grant to support the construction of a HUF 3.78bn R&D base. The base is expected to be completed by December 2010. Twenty new research jobs will be created at the 3,500-square-metre base, which will be staffed by 70 people. The new base is expected to cut the time new products are brought to market by 15pc, or about six months. The base will increase by 50pc the number of generic products Egis develops each year. Until now, Egis has made 2-3 such products a year. Egis spends an annual HUF 8bn-9bn on R&D each year. The company employs 2,600 people in Hungary.

## Life sciences research and development is centred aroung four major cities of Hungary: Budapest J. Szentágothai Ctr.

Cell Communication Kn. Ctr. Central Hungarian Kn. Ctr. Inst. of Experimental Medicine Number of science students: 20,000

Pécs Medinolis Kn. Ctr. Health Care Innovation Ctr. Pannon Incubator House Number of science students: 15.000

Biopolisz Cluster Neurobiological Kn. Ctr. Number of science students: 10,000

#### Pharmagora Cluster lays corner stone of HUF 574m R+D centre

A consortium of eleven SMEs called the Pharmagora Quality of Life Cluster on Friday laid the cornerstone of a HUF 574m R+D centre in Balatonfured (NW Hungary). About HUF 287m of the cost of the investment came from European Union and state grants. Pharmagora is the seventeenth accredited cluster in Hungary.

GenoID prides itself in being a leader in HPV diagnostics research. The company is developing technologically advanced, user-friendly and trusted products which fit in various laboratory environments. GenoID is also the laboratory of choice for a growing number of European gynaecologists seeking high-quality and cost-efficient HPV typing and STI diagnostic service. GenoID's real-time PCR high-risk and low-risk HPV assay received the Frost & Sullivan Product Innovation Award in 2006. "Despite being a small company, Hungary-based GenoID has perceptively leveraged its expertise to create unique product ranges and effectively penetrate the competitive European molecular diagnostics market." Arun A.K. // Frost & Sullivan Research Analyst

Debrecen

Pharmapolis Cluster Genomenanotech Kn. Ctr.

Number of science students: 7.000

Molecular Medicine Res. Ctr.

- University of Szeged The second largest education and research centre in the country.
- The centre of biotechnology research in Hungary: 180 R&D locations, over 1,500 people
- Szeged Neurobiological Knowledge Centre (DNT): Therapy-oriented neurobiological research, from the molecule to the integrated functioning of the nervous system.
- Szeged Biopolisz Pole Program: a well structured programme to create an ideal research location.

#### Debrecen

- With 30,000 students and 23 PhD schools, the University of Debrecen is not only the oldest, but also one of the top universities in Hungary.
- Approx. 200 million EUR have recently been spent on new buildings, renovations and technical developments at the university, including the Life Science Centre for molecular medicine, biology and agricultural sciences.
- Genomnanotech University Knowledge Centre: cutting-edge technologies are developed at the Debrecen University and its region, including genomics, nano- and biotechnologies. Its fifteen industry partners include companies such as National Instruments, Solvo Biotechnology and AMRI Hungary.
- A Pharmapolis Cluster is under development with the cooperation of the university, local companies and the City of Debrecen.
- The Research Centre of Molecular Medicine was recognised as a "Centre of Excellence" by the European Union in 2004.
- Ten university spin-off companies are presently incubated in the Bio Incubator Centre.

#### Pécs

- The University of Pécs is one of the largest institutions of higher education in Hungary with one of the widest ranges of academic courses and research projects. The university has 35,000 students and 10 faculties.
- Medical high-tech industry, based on biotechnological research, is already present in the region.
- Four main sectors within the biotechnological industry in the region:
  - Research into reagent and diagnostic methods
  - Development of instruments
  - Biotechnology R+D in connection with environmental issues
  - R&D in dietetics
- One of key research sectors in the region is the industrial and medical ap-
- Medipolis Knowledge Centre, University of Pécs. Development and production of medical polymers for painful conditions and pain-killing and anti-inflammatory drugs in cooperation with Biostatin, Richter and Roche
- Pannon Incubator House provides a state-of-the-art infrastructure for small and mid-sized companies. It also hosts the Pannon Laser Centre.
- By 2011, a Healthcare Innovation Centre in Pécs will be established in the local industrial park to create a bridge between market-driven product development and the research sector.

#### Follow the others

In 2006 September, GlaxoSmithKline opened a EUR 100 million vaccine production plant in Gödöllő, a Hungarian city 30 km north-east of Budapest. The site is one of Europe's most advanced biotechnology plants and manufactures two types of vaccine, one of which is DPT, a combination of three vaccines to immunise against diphtheria, pertussis and tetanus and exported to developing countries under a WHO initiative.



The Hungarian city of Debrecen provides the location for **Gedeon Richter** Plc.'s new investment project to establish a plant, with total expenditure exceeding HUF 15 billion, for the development and manufacture of biopharmaceutical products. Besides the new manufacturing unit being a milestone in the realisation of Richter's strategic goals, it is also a significant step forward in enhancing the competitiveness of Hungarian industry and thereby that of Hungary, too. Richter's unit in Debrecen will be one of kind in Central and Eastern Europe.

Hungarian-owned ThalesNano Inc. and Sanofi-Aventis R&D collaborate on continuous process chemistry in order to dramatically reduce drug realization time. The collaboration will focus on the development and implementation of continuous process technologies from research to full scale production. The purpose of the project is to study the utilization and application of ThalesNano's integrated continuous process chemistry technologies within the Sanofi-Aventis drug R&D process from discovery to API production.

"We are delighted to work with Sanofi-Aventis R&D who have always been at the forefront of applying new methods and technologies to improve the drug discovery and development process. The ThalesNano continuous process technology is already well established in the discovery labs of the life sciences industry. Taking it to process scale promises tremendous benefits for our customers in terms of reducing development time, increasing cost efficiency and minimizing environmental impact." // dr. László Ürge, CEO, ThalesNano Inc.



#### Cyclodextrine - industrial material

CycloLab Kft.'s project developes develops new pharmaceutical formulas with the help of second generation cyclodextrins. The aim of the research is to find the proper cyclodextrin and the optimal conditions for manufacturing well-balanced pre-formulations for pharmaceutical applications. The inclusion complex formation with various substances has also been utilized in case of environmental and analytical applications, catalysis, etc. This mechanism is to be studied using the most up-to-date methods of molecular biology as well as to find and prepare the proper second generation cyclodextrin derivatives.

#### ChemAxon

A leading provider of cheminformatics software for the life sciences industry has entered into agreement with Pfizer to provide its Markush searching and structure enumeration functionality for global development and deployment within Pfizer's global R&D facilities. The company is a leader in providing cheminformatics software development platforms and applications for the biotechnology, pharmaceutical and agrochemical industries. With core capabilities for structure visualization, search and management, property prediction, virtual synthesis, screening and drug design, ChemAxon focuses upon active interaction with users and software portability to create powerful, cost effective cross platform solutions and programming interfaces to power modern cheminformatics and chemical communication.



#### **BGP-15: Prevention of metabolic adverse** effects of anti-psychotic drugs

N-Gene Research Laboratories, Inc. ("N-Gene") is a pharmaceutical company with a pipeline of proprietary drugs to treat insulin-resistance syndrome, improve cancer chemotherapy, prevent skin cancer, and slow skin aging. BGP-15, N-Gene's lead compound is a new type of insulin sensitizer whose efficacy in preclinical studies is comparable to that of market leader drugs widely used in the treatment of Type 2 diabetes. N-Gene's second lead compound, NG-SUN, is a photoprotection and antiaging product. The latter was successfully tested in a human clinical trial by Dior, member of the LVMH Group.

#### **Unique Microdialysis Services at SOLVO Biotechnology**

SOLVO Biotechnology is the word wide pioneer in introducing drug-transporter specific brain microdialysis (MD) studies. The new microdialysis service is an integral part of SOLVO's BBB package. The package consists of an assortment of cross validated in vivo and in vitro tools for studying the drug transporter and/or drug-drug interactions in this important barrier. The BBB package focuses on two key efflux transporters: MDR1 and BCRP.

#### **Genetic Immunity**

An innovative biotechnology company developing plasmid DNA based Nanomedicine vaccines for infectious diseases, allergy and cancer. They have three platform technologies: antigeneering of VLP; nanoformulation of antigens and DermaPrep a CE marked topical medical device to deliver nanomedicines to the lymph nodes. Their lead product, DermaVir Patch against HIV/AIDS showed in human phase clinical trials excellent safety and immunogenicity profile in all treated HIV+ individuals. DermaVir Patch is recently in Phase II clinical stage. GI expect the efficacy data from three (US and EU) clinical trials in Q2 2010. Based on their nanomedicine platform technologies the company has therapeutic vaccines against Chlamydia infection and dust mite allergy in preclinical development and against HPV in discovery stage.



#### MediMass

A technology start-up created to develop and market a unique medical device that allows instant differentiation of cancerous and healthy tissue where it is most needed – in the operating theatre. By providing real-time information to surgeons on the tissue they are cutting, the product facilitates improved decision-making and precision, thereby ensuring higher survival rates, lower risk of relapse and considerably fewer subsequent interventions. The MediMass technology, based on the use of chemical information inherent in tissue, is particularly useful for operations of delicate areas, such as skin, breasts and testicles, as it reduces the need for plastic surgery and postoperative patient care. Alpha testing of the product is currently under way and fully functional prototype devices are already in use in veterinary practices.

**TEVA Hungary** built a EUR 75 million factory for the production of active pharmaceutical ingredients (APIs) in Sajóbábony, Hungary. Between 60 and 100 people will be employed at the facility, and its production will be mostly exported. With the help of companies like TEVA, Hungary is developing its pharmaceutical exports industry well. TEVA began manufacturing in Hungary in 1995 and now employs 2,400 people there.

"Teva, the world's leading generic pharmaceutical company, is continuously developing its research facilities and manufacturing capacity in Hungary. The productivity and expertise of Teva's Hungarian workforce have prompted the company to choose Hungary as a location for its largest investments of recent years."





BD (Becton, Dickinson and Company), a leading global medical technology company opened a new production facility in Tatabánya. Construction of the €100 million, state-of-the-art facility began in 2008, and production is expected to start later in 2010. BD is expected to employ approximately 500 people at the facility by 2014. BD pioneered the production of prefillable injection devices and continues to be a global leader in the field. The new plant will help meet the growing worldwide demand for the prefillable syringes that are sold to pharmaceutical and biotechnology firms whose injectable drugs are delivered using these devices.

"BD chose to establish this important production facility in Hungary because of the proximity to the important European customers it will serve. The availability of a highly skilled workforce, access to qualified subcontractors, and the support of local public officials were also key factors in our selection of this attractive location for BD's new manufacturing presence." // Claude Dartiguelongue, President, BD Medical – Pharmaceutical Systems

In February 2010, **Ceva-Phylaxia**, revealed the latest in a long series of recent investments with the opening of a new bacterial vaccine plant supported by the Hungarian State. The new facility will produce innovative aerobic and anaerobic new bacterial vaccines for Ceva's growing global demand. The EUR 8.5 million plant takes combined investment in the Budapest campus to over EUR 28 million since the programme began in 2002. Ceva-Phylaxia, a unit of French veterinary drugs company CEVA Sante Animale, currently employs 330 people with an R&D team of over 90 people. Ninety percent of the Company's production is exported to countries throughout the world. Ceva is now the number 1 global producer of vaccines against the Gumboro poultry disease (and worldwide number 3 for poultry vaccines), with its innovative immune complex vaccine CEVAC TRANSMUNE IBD. The Budapest site also produces COXEVAC – Ceva's breakthrough vaccine for the control of Q-fever, a zoonotic disease that has recently caused much concern throughout the European Union, with a serious outbreak of the disease in the Netherlands during 2009.

### Key players

About 150 biotech enterprises, five biotech-related university knowledge centres and three bio incubators are clustered in four academic towns.

#### **Budapest region**

- 3DHISTECH www.3dhistech.com
- 77 Elektronika www.e77.hu
- Alpharma www.alpharma.com
- AMRI Hungary www.amriglobal.com
- Applera Hungary www.appliedbiosystems.com
- Argint International
- www.argintinternational.com
- Assign Hungary Clinical Research
- www.assigngroup.com
- Auricoop www.trc.hu
- Bay Zoltan Foundation for Applied Research - www.bzaka.hu
- Béres Pharmaceuticals www.beres.hu
- Biogreen www.biogreen.hu
- Biolab www.biolab.hu/profil.htm
- BioMarker www.biomarker.hu
- Biomi www.biomi.hu
- Bio-Rad Hungary www.bio-rad.com
- Biosan www.biosan.hu
- Bio-Science www.bio-science.hu
- Biostatin www.biostatin.hu
- BioSystems International www.biosys-intl.com
- BioTalentum www.biotalentum.hu
- Biotechnology Hungary
- www.semmelweisinnovations.com
- Biropharma www.biropharma.com
- Bitrial www.bitrial.hu
- Cemelog www.cemelog.hu
- CEVA-Phylaxia www.ceva.com
- CF Pharma www.cfpharma.hu
- ChemAxon www.chemaxon.com
- Chinoin (Sanofi-Aventis) – www.sanofi-aventis.hu/live/hu/hu/index.jsp
- ComGrid www.comgrid.hu
- ComInnex www.cominnex.com
- Convincive Consulting www.convincive.hu
- Cryoinnovation www.cryo-innovation.com
- Cyclolab www.cyclolab.hu
- Danubia www.danubia.hu
- Diagnosticum www.diagnosticumltd.eu
- Diagon www.diagon.com
- Diatron www.diatron.com
- EGIS Pharmaceuticals PLC www.egis.hu
- ERDŐ PHARMA www.erdopharma.hu
- e-spell nonstop www.espell.com/

- Evonik Agroferm JSC www.evonik.com
- Experimetria www.experimetria.com
- Fermentia www.fermentia.hu
- Gebauer Pharma Ltd. www.gebauerpharma.hu • Genetic Immunity – www.geneticimmunity.com
- GenoID www.genoid.net
- Genzyme Hungary www.genzyme.com /global\_locations/us/us\_global\_locations.asp
- GlaxoSmithKline www.gsk.hu
- Goodwill Research www.goodwill-research.com
- Hospinvest Diagnostics www.dq-hospinvest.hu
- Humán Bioplazma Ltd. www.kedrion.com/ ENG/where we are worldwide production.html
- Humet www.humet.hu
- HungaroTrial www.hungarotrial.hu
- HYD www.hyd.hu
- InFarmatik www.infarmatik.com
- Institute of Isotopes www.izotop.hu
- ISH www.ish.hu
- Kemiome www.kemiome.com
- KPS Biotechnology www.kps.hu
- KRIO www.krio.hu
- LGC Promochem www.lgcstandards.com
- L&MARK www.lmark.hu
- Lab-Intern www.labintern.hu
- Megapharma www.megapharma.hu
- Monsanto www.monsanto.com
- NanGenex www.nangenex.com
- N-Gene www.ngene.us
- Omninvest www.omninvest.hu • Pharmateka – www.pharmateka.hu
- Pioneer Hi-Bred Hungary
- www.pioneer.com/hungary
- Reanal www.reanal.com
- RecomGenex www.recomgenex.com
- Richter Gedeon www.richter.hu
- Roche Hungary www.roche.hu
- Semmelweis Innovations
- www.semmelweisinnovations.com
- SeroScience www.seroscience.com • Sigma-Aldrich — www.sigmaaldrich.com
- SINNEX www.sinnex.hu
- Solvo www.solvo.com
- SPSS Hungary www.spss.hu
- Syngenta www.syngenta.hu
- TargetEx www.target-ex.com
- Thales Nanotechnology www.thalesnano.com
- Tomtec www.tomtec.hu
- TóPARK Sales and Information Center www.topark.eu
- Trigon www.trigon-rt.hu
- Ubichem www.ubichem.com
- Unicorp Biotech www.unicorp.hu
- ValDeal Innovations www.valdeal.com
- Vichem Chemie www.vichem.hu
- Vitaminkosár www.vitaminkosar.hu
- Vitamin Station www.vitaminstation.hu

- Weck Ap Ltd. http://www.weck-ap.hu
- Wessling Hungary Ltd. www.wessling.hu
- Wold Health www.antigen.hu

#### Debrecen region

- Abiol www.abiol.com
- Adexgo www.adexgo.hu
- Agroferm www.aminoacidsandmore.com
- AMD www.pharmapolis.hu
- Analab www.analab.hu
- Astrid Research www.astridresearch.com
- BIOMER http://gnd.unideb.hu/gnd/biomer.html
- BioSystems International www.biosys-intl.com
- Biropharma www.biropharma.com
- CERA-MED http://gnd.unideb.hu
- CETOX http://puma.unideb.hu/~cetox
- ClinTrial www.clintrial.com
- DENEX http://gnd.unideb.hu/gnd/denex.html
- Flavon Group www.flavonmax.hu
- Genomnanotech Regional University Knowledge Centre - http://gnd.unideb.hu
- Innotears www.innotears.hu
- Spektrum-3D Ltd. www.spektrum-3d.hu
- Teva Pharmaceutical Works Ltd. www.teva.hu
- UD-GenoMed Ltd. http://ud-genomed. hu/?lang=2

#### Szeged region

- AVICOR www.avicorbiotech.com
- Avidin www.avidinbiotech.com
- Biochip www.biopolisz.hu
- Biofotonika www.biopolisz.hu
- BIOPOLISZ www.biopolisz.hu • Creative Labor – www.creativelab.hu
- Goodwill Pharma www.goodwillpharma.com
- LipidArt www.lipidart.com
- Pharmahungary www.pharmahungary.com
- PRONOVIX http://pronovix.com
- Segomics www.segomics.hu
- Solvo www.solvo.com
- Szeged Neurobiological Knowledge Center – www.konturweb.hu/dnt/index.php
- Transmetrix www.transmetrix.com

#### Pécs region

- Adware Research www.adwareresearch.com
- BIOTECONT www.biotecont.hu
- DRC www.drc.hu
- Histopatology www.histopat.hu
- Innovum www.innovum.hu
- LAB International Hungary www.labinc.hu
- Pannonpharma www.pannonpharma.hu
- PEIK www.peik.hu Soft Flow – www.softflow.com



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### **Hungary's One-Stop Shop for Business**

The **government's investment and trade development agency** was established in 1993 to promote inward investments and bilateral trade. With representative offices in eight regional centres of Hungary and a foreign network operating under Hungary's diplomatic services and by special assignments in 60 countries, ITD Hungary is a **single point of contact** to support decision-makers looking for new business opportunities in Hungary.

#### For investors

- In-depth, tailored information on the local economy and the legal environment; sector-specific overviews
- Liaising with local and central authorities, suppliers and service providers
- Information and advice on available incentives and finalisation of incentives agreements
- Assistance in accelerating permitting procedures, recruitment and visa procedures
- Support and generation of reinvestments
- Promotion of Hungarian direct investments abroad

#### **Trade Promotion**

Through a diverse set of marketing tools and support programmes, ITD Hungary offers substantial **logistical**, **financial** and **professional** assistance to both start-up and established Hungarian exporters. The Agency also co-ordinates the Hungarian activities of the Enterprise Europe Network, which, with a focus on innovative enterprises and innovation-related sectors, offers support and advice to SMEs across Europe and helps them make the most of opportunities in the European Union.

#### Communication

The Agency arranges **business programmes** for individual visitors and delegations, and organises awareness and networking business events. ITD Hungary develops and distributes **printed and electronic business literature** in a variety of languages. Subscribe to ITD Hungary's electronic weekly Newsletter and/or order a free copy of HINT, its quarterly business magazine published in English and German, at editor@itd.hu.

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