

Producing drugs in Poland: Bioton (Warsaw)

Eastern Growth

Warsaw, capital of Poland, is one of its industrial and financial centres. Biotechnology is developing rapidly here. Over the last two decades, Bioton S. A. has evolved from a biotech to a pharmaceutical company.

Bioton was incorporated in 1989 as the operator of a cephalosporin plant in Łódź. In 1993, it was taken over by the Institute of Biotechnology and Antibiotics (IBA) and transformed into a company distributing the Institute's products. IBA became, therefore, the progenitor of Bioton in its present shape. After 1993, Bioton began the operations which form the backbone of its activity today. The breakthrough point for the company was its project addressing the development of recombinant human insulin. The project, to develop the relevant technology and launch the pro-

duction of the first modern biotechnology drug in Poland based on genetic engineering and protein recombination, was initiated by IBA. The project was co-financed by Prokom Investments, a venture capital firm from Warsaw, and the State Committee for Scientific Research. The company was restructured into a joint stock holding on 2nd August 2004.

Since 16th March Bioton S.A. shares have been quoted on the Warsaw Stock Exchange. At present, it is the only biotechnology company listed on the Warsaw Stock Exchange in the WIG20 index, which illus-

trates the value development of the 20 biggest Polish stocks. In the 2006 top 50 ranking, prepared by IMS Health, a U.S. consulting and market research company, Bioton was listed as one of the five most dynamically developing companies in the pharmaceutical sector by pharmacy sales.

Recombined human insulin as a main product

Bioton manufactures drugs. Their main product is recombined human insulin in pharmaceutical form and as a preparation for injection. "We are belonging to the



Bioton's marketing team (from the left): Jacek Durczak, Jan Podhorecki, Jerzy Barbachowski, Ilona Jankowska, Oliwia Bozek, Małgorzata Krupa, Agnieszka Dalidowicz, Justyna Kloczko, Marcin Wilczęga, and Artur Mróz-Gonçalves

small groups of companies in the world that manufacture this substance," explains CEO Adam Wilczega. "We required 12 years from 1989 to 2001 for introduction onto the Polish market." Production was developed together with the Institute of Biotechnology and Antibiotics (IBA). It was the first East European biotechnological drug manufactured using gene recombination techniques. "A co-operation with the IBA for several decades has been committed to the fundamental research into the development of drugs via biosynthesis and chemical synthesis," says Wilczega.

Bioton is also active in the antibiotics business: aminoglycosides for injection, cephalosporines for injection and oral administration, oral macrolides and so on. Besides this, the IBA is a manufacturer of preparations with anti-cancer properties derived from the anthracycline group and used in therapies for many kinds of cancer (including cancers of the lungs, the bladder, and of the haematopoietic and lymphatic systems).

Bioton had gained more than a 26 percent share of the Polish market for classic insulin by the end of June 2006, meaning that the company is the leading distributor and producer of human insulin in Poland. "We are planning to sell insulin in the global market through a joint venture in selected growing markets and through concluding distribution contracts," reports Wilczega.

Expanding into eastern markets

At the moment, Bioton exports insulin to India, Pakistan, the Philippines, Kyrgyzstan and Uzbekistan. The drug has also been licensed in Egypt, Belarus, Ukraine, and Vietnam. Licensing is anticipated in Russia, China and other Asian countries. Central registration for the markets of the "old" European Union is being undertaken in cooperation with international partners.

"A cooperation with Diosynth Biotechnology, which is located in the Research Triangle Park in North Carolina will open up the market of Southern and Central America, North Africa and the countries



Bioton's Warsaw labs. Since 2001, the Polish biotech company is producing recombinant human insulin in pharmaceutical form and as a preparation for injection here. Even though most batches of the drug go to Asian markets as India and Pakistan, Bioton also eyes Europe and Southern and Central America as well.

of Middle East," says Wilczega. Diosynth is a very well established company in insulin markets. The company has been isolating and producing insulin from bovine pancreases since 1923 and from porcine pancreases since 1930. "A registration for the European Union is in process," adds Wilczega. Manufactured antibiotics have also attracted the attention of the world pharmaceutical market and are currently sold in countries such as Russia, Belarus, Lithuania, Georgia, Azerbaijan, Ukraine and Vietnam.

Acquisition of Biopartners Holding

"Furthermore we have acquired the Swiss company Biopartners Holding, located in Baar near Switzerland's capital, Zurich," says Wilczega.

That was in 2007. Through the purchase of Biopartners, Bioton gained access to biotechnological products at advanced stages of development and to highly profitable European and American markets. The purchase of Biopartners enabled ear-

lier entry into the human growth hormone market than was originally planned.

Thanks to its acquisition of Biopartners, Bioton has five new drugs in the pipeline: First of all, the recombinant human growth hormone (rhGH) Valtropin, that was granted approval by the EMEA in April 2006, and another rhGH to combat growth hormone deficiency (in late clinical phase III). A submission to the EMEA for market authorization is planned for late 2009.

Bagging five advanced products

Two interferons were also included within the Biopartners acquisition: A β -interferon drug for multiple sclerosis will be submitted to the EMEA in 2007, and an α -interferon for chronic hepatitis C had its clinical development completed. Finally, a synthetic nucleoside analogue of guanosine with anti-viral effect for the treatment of hepatitis C (called Ribavirin) has completed its clinical development.

Target markets for these drugs are the European Union, CIS countries, Australia



Feeding in the next big deal? Bioton's Chairman, Adam Wilczega, is oozing contentment and searching for new markets.

and Japan, and growth plans include acquiring the global distribution rights to β -interferon.

Bioton has completed the transition from a biotech to a pharmaceutical company. "Currently we are specialising in the production of recombinant proteins, their biosynthesis, and the production of pharmaceutical drugs. Biopartners' know-how will support this process. Our inten-

tion is to systematically increase the share of medicinal products based on substances produced via biosynthesis. The aim is to create an attractive portfolio that will include high-margin products of a high therapeutic efficacy," says Wilczega.

By the end of 2006, the Bioton Group's net profit had increased to 96.5 million złoty (the equivalent of approx €26.3 million), a rise of 188 percent in comparison to 2005. Sales revenue last year reached almost 214 million złoty (€58.3 million) in comparison to 152 million złoty in 2005 (up 41 percent).

Dreaming about global strategies

"We have a lot of reasons to be satisfied. The dynamic sales growth on the domestic market and export growth have enabled the company to end 2006 with profit several times higher than in the previ-

ous year. I think that Bioton has achieved a wonderful result. We have also been consistently carrying out our global development strategy by building our presence in new markets," said Wilczega.

Besides insulin, further drug projects include clinical research into growth hormones, the development of interferon medication, pre-clinical research into insulin analogues, and the preparation of registration documentation for the Erythropoietin (EPO) and Granulocyte Colony-Stimulating Factor GCSF.

Beside industrial business, Bioton also follows the golden marketing rule of "Act well and make it known!". The company operates community programmes such as training for nurse-educators, and sponsors the nationwide social programme for diabetes prophylactics. Since January 2007 Bioton has been the sponsor of the Polish national swimming team, which is going for gold at the 2008 Olympic Games in Beijing.

KAY TERPE

Polish biotech companies

A Certain Breath of History

Besides Bioton S.A. (see above), there are numerous other biotech companies in Poland. Here are eight.

Akwawit (Leszno) started making bio ethanol in 1950. The Polish bio ethanol market has increased over the last decade and at present Akwawit is the biggest bio ethanol producer in Poland. Furthermore, the company offers a wide range of chemical and microbiological analyses, and produces pure vodkas.

Bio-Gen (Warsaw) is a diagnostics company. The focus is on the medical diagnosis of Alzheimer's, Parkinson's and other diseases. Furthermore, the company is active in forensic medicine, cancer, medical microbiology, allergies, and paternity tests.

Biomed Lublin (Lublin) was founded during the Second World War in 1944. The complicated epidemiological situation at this time made preventing the spread of contagious diseases essential. In 2001 the company was passed into private hands. The current employment level is

approximately 230 people. The company has specialized in the manufacture of many therapeutic preparations.

Biomed (Warsaw) Sera and Vaccines Production Plant belongs to the group of companies that produce sera, vaccines and other biopreparations that are indispensable for medical diagnostic procedures, epidemiology and fighting infections. The plant takes pride in its history of over 50 years. Between 1951 and 1997 it was part of the Ministry of Health and Social Welfare. Presently, its boss is the Governor of Mazowze Province.

Biowet (Drwalew) is a joint stock company with an established market position among manufacturers of a wide variety of medicines for animals in Poland. Their roots reach back to 1929. Products include chemotherapeutics and biopreparates.

BTL (Lodz) was founded in 1990. The biotech focus of the company is the production of culture media and the analysis of biochemicals. Furthermore, the company is active in molecular biology and microbiology.

DNA-Gdansk (Gdansk) is a research-based company. It produces and sells equipment and services for molecular biology, biotechnology, genetics, and molecular diagnostics.

IBSS Biomed (Krakow) has 60 years of experience in pharmaceuticals. The company, which originally emerged from the Medical Microbiology Institute of Jagiellonian University in Krakow was in 1998 transformed into Biomed Krakow, which was converted into a joint-stock company in 2001. In 2003 the company changed its name to IBSS Biomed.

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