



CEO of GEROPHARM
Petr Rodionov

GEROPHARM is one of the TOP-20 leading Russian pharmaceutical producers. The company's dynamic growth since its incorporation in 2001 allowed it to become one of the prominent members of the pharmaceutical market and an expert in the pharmaceutical community.

GEROPHARM was included in the TOP-30 fastest growing high-tech Russian companies in the 2012 rating "TekhUspek".

The company is a resident of the Saint Petersburg pharmaceutical cluster and a biopharmaceutical cluster in Moscow Region. It is also a member of the Association of Russian Pharmaceutical Manufacturers, Russian Chamber of Com-

merce, and non-commercial Partnership "XXI Century Medical and Pharmaceutical Projects".

GEROPHARM group of companies includes:

- **GEROPHARM** Ltd – a leading company, determining the development strategy and is engaged in the production and distribution of drugs,
- **OJSC GEROPHARM-Bio** (formerly National Biotechnologies) – the first in Russia commercial producer of human insulin,
- **CJSC Pharm-Holding**, involved in a full-cycle development of drugs, organization of pre-clinical and clinical research, testing of new technologies and their application in industrial production. The group is headquartered in Saint Petersburg, whereas its representative offices are based in 75 locations on the territory of the Russian Federation and CIS countries: in Belarus, Ukraine, Kazakhstan, Georgia, and Azerbaijan. Strategic targets of the group are in line with the main goals of the pharmaceutical industry realized within federal programs "PHARMA - 2020" and "BIO - 2020."

GEROPHARM is the only manufacturer of original drugs Cortexin (effective neuroprotective drug) and Retinalamin (ophthalmic drug stimulating retina regeneration). The company has recently released generic preparation Levetinol

used in the treatment of various forms of epilepsy. OJSC GEROPHARM-Bio produces drugs for the treatment of diabetes – Rinsulin R and Rinsulin NPH. The quality of the substance meets the requirements of British and American



Pharmacopoeia. The company's portfolio also includes a diagnostic kit – GEB-IFA-Test determining the extent of damage to the brain and central nervous system in brain injuries. It is supplied to the leading scientific centers of the country.

On 2 October 2013, in Serpukhov district, Moscow Region, a modern, high-tech complex OJSC GEROPHARM-Bio, the first Russian full-cycle production of recombinant human insulin was opened. The company is unique in Russia, as it supports the country's drug safety by locating all stages of the socially important drugs production in the country thus ensuring its independence from foreign suppliers. One of the results of a successful cooperation between GEROPHARM and Saint Petersburg cluster was opening in December 2011 of a research center in the Saint Petersburg free-economic zone Neudorf. The aim of the investment was to support the expansion of the product portfolio of GEROPHARM, modernization of the industry as a whole, and the Russian market's saturation with modern, effective



drugs. In 2013, the total area of GEROPHARM's research complex was 2-fold increased and now consists of 1500 m².

Information actions as one of the preventive measures to stop the increase of incidence of socially-significant is one of the priorities of GEROPHARM. Every year the company organizes social events during which it informs the public how to prevent diseases such as diabetes and glaucoma, as well as helps in rehabilitation and socialization of people suffering from neurological diseases. In 2010-2011, a series of round tables for journalists devoted to the problems of socially important diseases were organized. In November 2012, the company initiated "Diabetes Day" in Serpukhov district, Moscow Region. In November 2013, GEROPHARM actively participated in the events associated with the "World Diabetes Day" organized in Moscow and Saint Petersburg. Given the enormous importance of the problem of diabetes in all aspects: economic, industrial and social, GEROPHARM organized a unique photo project: "Diabetes in persons" in order to draw attention to the problem. The pictures were taken by Valery Plotnikov, a famous Russian photographer. We talk to Petr Rodionov, SEO of GEROPHARM, a winner of the title "The Chief of the Year 2013" in the nomina-

tion "Chief Innovation", a Member of the Supervisory Board of the Association of Russian Pharmaceutical Manufacturers, Non-Profit Partnership "XXI Century Medical and Pharmaceutical Projects", and Russian Public Organization "Business Russia."



Q: Why it was decided to build a plant producing insulin?

A: Endocrinology is one of the areas in which GEROPHARM specializes. OJSC GEROPHARM-Bio was originally formed to carry out an ambitious, national task: creating the technology of production of recombinant human insulin under the program "Diabetes Mellitus." Today we possess technology enabling to run a full cycle of production of essential drugs: from substance to finished dosage form. Industrial production of insulin is practically a new business for us. We already produce a range of insulin –

recombinant drugs, but there are more modern forms, still protected by patents, currently developed under federal targeted programs. We are waiting for their completion to apply for registration. This year we plan to start the production of insulin injection pens. It will be done at a production site of our new plant in Obolensk.

Q: How long did it take to build the plant?

A: This is a major investment project, implemented in a relatively short period of time: the construction began in 2011, and already in October 2013 gala-opening ceremony took place. Our strategic goal is to create a modern pharmaceutical infrastructure since the growth of the new industry coincides with the main assumptions of the federal strategy PHARMA - 2020, focused on the modernization and import substitution.

Q: What was the investment volume?

A: Investments amounted to RUB 1.5 billion, approximately 80 percent of which constituted our own funds. We also received support from banking structures – EBRD and Sberbank.

Q: Currently Good Manufacturing



Practice (GMP) is a very popular topic in Russia - these standards became mandatory since 1 January. Will it help your company to compete with foreign manufacturers?

A: We came into pharmaceutical market as a serious player for a long period of time. Furthermore, we aim to work not only in the Russian market but also internationally. Pharmaceutical market became global a long time ago. Therefore, while investing in the development and manufacture of new drugs, we certainly do not limit our plans to Russia, we have much bigger ambitions. Therefore, while planning our new production facility,



from the very beginning we were taking into consideration its compliance with relevant GMP requirements, long before they became mandatory in Russia. Moreover, it is a unique production for Russia – here for the first time the full cycle of the production of recombinant insulin is applied (from synthesis of substance to finished dosage form). Technological design was done with the participation of leading European organizations, and equipment supplied by world leaders was installed. The pro-

duction is automated to the maximum – even the quality control at some stages is performed by automated inspection machines that thoroughly check each bottle for small inclusions. In total, there is over 1000 control points in the production cycle. In May 2013, the plant GEROPHARM-Bio passed the certification audit which confirmed its compliance with ISO 9001:2008 international standard as well as national standard GOST ISO 9001:2011. One can say that the new plant became one of the points of growth and competence in the industry. Speaking of competition – we are not afraid of it. Moreover, we are for the development of competition – open and transparent – since it only to benefits the market.

Q: What, in your opinion, is more important for the success of the project – equipment or staff?

A: Is that a correctly asked question? Both factors are important but without a good team you will get nowhere. Equipment, even the best, is just a tool which should be used by the right professionals. We like to introduce young people to the team: caring, open to new ideas, with passion. It is easier to teach them the GMP philosophy. Today, the plant employs over 200 people, the majority of whom are young persons.

Q: How large-scale is new production?

A: The area of the plant covers approximately 10,000 m². Here are the

workshops in which biosynthesis of substance is carried out, as well as automated industrial line for the production of finished dosage forms. In 2014 we will start the production of insulin injection pens and this project will also be implemented at this site. The plant's production volume is estimated at up to 25 million bottles and 5 million of cartridges per year.

Q: Will you produce here other preparations, instead of insulin?

A: Yes, we plan to release here modern preparations for the treatment of socially significant diseases, including diabetes, the development of which is being carried out in our research center in the Special Economic Zone Neudorf.

Q: Are you planning to build new production facilities?

A: Yes, we are currently implementing a project in Pushkin. It will be another high-tech industrial complex with a fully automated production and quality control system, in accordance with international GMP standards. We are planning to produce here substances, solid dosage forms and pre-filled syringes.

FACT BOX



FULL NAME:

Group of the company GEROPHARM

CEO:

Petr Rodionov

OPERATIONS:

Pharmaceutical company

ESTABLISHED:

2001

EMPLOYEES:

more than 600

www.geropharm.com

