# **BIOCAD**

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# Leading innovative biologic and smallmolecule therapeutic development in Russia

BIOCAD, the leading Russian biotechnology company, owns a robust portfolio of globally marketed products and is focusing its efforts on research and development of novel compounds and biologics, primarily for oncology. Building on its national leadership position, the company is seeking to expand its international presence through joint clinical development partnerships.

BIOCAD, an innovative Russian biotechnology company with a large global footprint, boasts ultra-modern pharmaceutical and biotechnological manufacturing facilities in Moscow and Saint Petersburg, as well as a world-class R&D center at the Neudorf Special Economic Zone in Strelna, near Saint Petersburg.

BIOCAD was established in 2001 with the goal of developing a one-stop destination for innovative biotechnology R&D projects—from basic science through clinical studies, all the way to production and commercialization.

Today, the company's portfolio includes more than 45 marketed products, 10 of them biologics, and over 40 drugs at various stages of development (37 biologics and 8 small-molecule compounds). In addition to leading the market with biosimilars and bio-betters, BIOCAD is focused on developing original drugs—next-in-class and first-in-class—for immuno-oncology, hematology and autoimmune disease treatment.

"Our goal is to bring affordable innovation to patients in need, in emerging markets as well as in developed countries. Our biosimilar mAbs [monoclonal antibodies] are approved and now marketed or in the process of registration in over 50 countries worldwide, mainly in Latin America, Southeast Asia and the MENA [Middle East and North Africa] region," said Roman Ivanov, VP of R&D at BIOCAD. He added, "We believe the high quality of our products combined with the low cost of development and goods can make our generic, biosimilar and original products very competitive in developed markets." BIOCAD aims to expand its global presence through cooperative R&D projects, particularly in the area of clinical development.

#### The BIOCAD advantage

From its inception, BIOCAD has differentiated itself from other biopharmaceutical companies by integrating all steps of and necessary competencies for the R&D cycle—including commercialization—under one roof, thus minimizing the need to externalize any part of the process and maximizing efficiency. This not only allows the company to plan and guide the R&D process more efficiently, but also provides BIOCAD with the flexibility to quickly react to the markets' needs and rapidly move into new therapeutic areas and modalities, such as chimeric antigen receptor (CAR) T cells and gene therapy.



**BIOCAD.** The leading Russian biotechnology company delivers advanced therapeutics in oncology, autoimmune disease and hematology.

The foundation for BIOCAD's strength is formed partly by its focused investments in fundamental science. A number of joint projects with the medical community of the Russian Federation speak to this commitment. In particular, the development of original first-in-class drugs is structured around a vast network of such collaborations and a streamlined licensing strategy.

Earlier this year, for example, BIOCAD initiated a phase 2 study of BCD-100, an innovative mAb targeting PD-1 for the treatment of melanoma, lung cancer, kidney cancer and Hodgkin's lymphoma. This year, BIOCAD is slated to start a phase 3 study of its mAb to interleukin-17, BCD-085, for the treatment of the autoimmune diseases psoriasis and ankylosing spondylitis.

"We started as a local biosimilar player with rituximab, trastuzumab and bevacizumab that had a dramatic impact on drug availability for Russian patients, and we predict that the upcoming launch of rheumatology biosimilars infliximab and adalimumab will have an even bigger impact," said Ivanov. "As for innovative projects, BIOCAD has proprietary phage display libraries that are among the best in the industry, and proprietary in silico structure-optimization algorithms. Now it is developing technology platforms for innovative AAV [adeno-associated virus]-based gene therapies and RNA vaccines," added Ivanov.

### International projection

BIOCAD is developing its international footprint beyond its current reach. With several drugs approved and being commercialized in different lowand medium-regulation markets, the company now wishes to implement new partnerships in Europe and the United States. Recently, BIOCAD established partnerships with the University of Turku, Åbo Akademi University and Turku Science Park Ltd. in Finland in education, fundamental research and commercial manufacturing. The company is interested in launching more such partnerships with European counterparts for the joint clinical development of BIOCAD's products.

BIOCAD is committed to the idea of manufacturing cost-effective drugs as an important cornerstone of strategies to help increase access to biologic medicines in emerging markets as well as in more developed markets such as Europe. With this in mind, the company has developed a pipeline of innovative biologic medicines, focusing on cancer immunotherapy—including several checkpoint inhibitors—one of the most advanced therapeutic approaches for cancer.

BIOCAD is ideally positioned to achieve this goal owing to its integrated structure and its ability to efficiently undertake all stages of the R&D process within the company and within the Russian Federation. This process is further supported by access to outstanding scientists and engineers who provide the necessary capabilities to carry out this process.

## MabNext and ChemNext

To propel the company to the next level, BIOCAD has launched two research programs of excellence: ChemNext for creating innovative chemical drug products, and MabNext for creating novel mAbs.

ChemNext has a portfolio of eight new molecules in oncology against known and novel targets. The goal of the program is to go from developing best-in-class to first-in-class molecules, and to integrate *in silico* modeling with high-speed synthesis and analytics.

MabNext has a portfolio of about 40 antibodies in oncology, autoimmune disease and cardiovascular disease. The program focuses on the development of antibodies with no non-human sequences and with high functional activity.

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