



Home Advantage

Catching up with its European and US counterparts, Russia is now looking to develop more innovative drugs domestically, with government-led schemes to support start-ups and encourage investment in biopharma firms from home and abroad

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Over the last decade, Russia has made a significant leap in biopharmaceutical R&D. After the fall of the Soviet Union in 1991, the country was virtually excluded from innovative drug development. The Russian market at that time was dominated by locally and Eastern Bloc produced generics, with only a limited number of patented medicines available. But the situation now is very different.

Total healthcare expenditure per capita has shown a significant and steady growth, from \$480.2 in 2002 to \$1,316.3 in 2011 (1). The market is flooded with pharmaceutical products, the clinical trial industry is rapidly expanding, and

the regulatory landscape is becoming more akin to European Medicines Agency and US Food and Drug Administration standards.

Yet Russia still lags substantially behind most developed countries in terms of healthcare spending. There is, however, an obvious natural demand for more investment and quality in the healthcare sector. The country's large ageing population and the prominence of cardiovascular and oncological conditions, combined with growing prosperity and medical awareness, make the situation similar to Europe and the US.

Pharma 2020

To address these needs, the Russian government has launched the Pharma 2020 programme, which specifies goals, spending and investment for the healthcare sector. In a bid to reverse the country's reliance on imported pharmaceutical products, the initiative aims to facilitate the domestic development and manufacturing of innovative drugs.

Among the programme's goals are to reach 60 per cent share of patented drugs in the portfolios of domestic manufactures by 2020, and to increase

the total sales share of locally produced drugs to 50 per cent (from 20 per cent in 2007) (2). Although many sceptics question the feasibility of these targets, the initiative is a tangible effort to tackle Russia's healthcare problems and boost biopharma and medical device development. Moreover, the expectations of further growth in healthcare spending have prompted many leading multinational companies, such as Pfizer, Novartis, AstraZeneca, Teva Pharmaceuticals and GlaxoSmithKline, to start investing in Russian manufacturing and R&D facilities.

Investment Funds

Amid its efforts to diversify the economy, the Russian government has initiated a number of state-backed investment funds which operate in the biopharma space. The RVC Biopharmaceutical Investment Fund, Maxwell Biotech Venture Fund, Rusnano and Skolkovo Foundation are funds with a defined strategy to help start-up companies transform promising scientific ideas with commercial potential into fully-fledged businesses.

These funds actively look domestically and abroad for attractive co-investment opportunities. There are, of course, some conditions attached: foreign companies must be willing to establish their R&D or manufacturing facilities in Russia and bring substantial economic potential or social benefit (3).

At the same time, many companies entering investment agreements have expressed their hopes for shorter study enrolment time, more flexible regulations, and other factors which can accelerate drug research and registration in the country.

Cooperation Examples

There are a number of interesting examples of investment cooperation in biopharma. Selecta (RUS) LLC – the Russian subsidiary of US-based Selecta Biosciences – along with its biopharma partner, BIND Biosciences, became Rusnano's first portfolio companies in the pharma sector to open a research centre in Russia (4). At the new facility, Russian and US scientists will develop immunotherapies and vaccines for the treatment and prevention of cancer, as well as respiratory, infectious, autoimmune and allergic diseases. The President and Chief Executive Officer of Selecta will move to Moscow to become the General Director of the Russian subsidiary.

Furthermore, in February 2014, BIND (RUS) – established in 2011 as a result of an investment agreement between Rusnano and BIND Therapeutics – announced the launch of a new R&D centre in Moscow. A key objective of the centre is to develop a new class of highly selectively targeted therapeutics (accurins) for the treatment of cancers and other diseases.

Another announcement from early this year concerns Heparera, a Skolkovo resident company funded by Maxwell Biotech Venture Fund, which has recently completed enrolment of a Phase 2 clinical trial of Myrcludex B. This innovative drug for the treatment of chronic viral hepatitis B and D originated from research at the University Hospital Heidelberg, Germany, and is being developed with the German biotechnology company MYR GmbH (5).

Routes to Success

The joint venture SynBio LLC – whose stakeholders include the Human Stem Cells Institute, Pharmsynthes, Cryonix, FDS Pharma LLP and Rusnano – is an example of Russian collaboration with British and German firms in innovative pharmaceuticals. SynBio has headquarters in Moscow and a controlling interest in research laboratories in the UK and Germany. The company develops nine medicines based on three biotech platforms – Histone, PolyXen and Gemacell – for the treatment of liver disease, cardiovascular disease, acute leukemia, growth hormone deficiency and diabetes mellitus (6).

Meanwhile, one of the most successful infrastructural investments Rusnano has made is BiOptix Diagnostics, a US-headquartered producer of biodetectors for drug tests whose technology was developed by 2005 Nobel Prize Laureate in Physics, John Hall.

BiOptix instrumentation allows researchers to study label-free protein-protein and protein-small molecule interactions, the measurements of which are essential for the development of promising molecular candidates for innovative drugs. In the latest move, the company is to open a Russian subsidiary, BiOptix Nanoprom, to produce its disposable bionanosensors and create an R&D presence in the Moscow region. It says that Rusnano's participation will hasten the process of building a successful business and enable it to tap into new, previously inaccessible markets and resources (7).



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Biopharma to Benefit from Planned Innovation City

In terms of investment and expectations, the proposed Skolkovo Innovation Center is one of the most fascinating projects currently unfolding in Russia. The project will see the construction of a 400-hectare site – a so-called ‘innocity’ – that is a hub of modern technological, including biopharma, development. The scheme, which is still in the planning stages, is being led by the Skolkovo Foundation, launched in 2010 with substantial governmental support.

Located near Moscow, the city will accommodate about 22,000 inhabitants and be an easy commute for a further 20,000 workers. Infrastructurally advanced, environmentally friendly and creatively designed, it will be based around two main features: the University and Technopark. Alongside laboratories, office buildings and a conference centre, there will be residential, recreational, fitness and store areas (9).

Start-Up Involvement

More than 1,000 start-ups are lined up to participate, of which about one quarter – or more than 250 registered companies – operate within biomedical clusters. The idea is not only to foster promising scientific ideas, but to facilitate the ultimate goal of bringing them to market. Whereas scientific advancement in Russia is historically highly esteemed – and primarily supported by the academic world – marketing and investment remain a weak link, which hampers successful commercialisation of products.

The project is governed by special legislation that will offer beneficial economic conditions for residents and employees at the site.

Project participants will be relieved from paying value-added, profit and corporate property taxes, and will benefit from a reduced rate on insurance premiums (10). In addition, they may be eligible for grants to fund their projects. There is also a simplified procedure to hire foreign employees, and virtually no visa and work permit requirements for foreign residents and their families based on-site.

Funding Needs

The project is expected to receive a total of \$15.2 billion of funding through 2020, from which \$4.1 billion is pledged from the state budget, with the rest coming from the private sector (11). Some \$1.2 billion will go to the development of the Skolkovo Institute of Science and Technology (Skoltech), which was established in collaboration with the Massachusetts Institute of Technology and has already welcomed about 70 students this year.

One of the criteria for the project’s effectiveness is the high proportion of private investment, compared to public funding. Skolkovo Foundation president Viktor Vekselberg has expressed hopes that it will not need government financing after 2025 (12).

However, with the project largely a state-led initiative, critics fear that the old Soviet tradition of governmental supervision could limit its success, and that it could fall foul to burdensome bureaucracy and funds embezzlement. Some recent events seem to confirm these concerns – for example, last year the project became entangled in a number of corruption scandals (13). High-level commitment is required to ensure the project achieves its ambitious aims.

Major Force

Joseph Damond, Senior Vice President of International Affairs at the Biotechnology Industry Organization, has commented: “Creating a more open trade atmosphere will encourage cross-border partnerships that will ultimately help to grow the industry in Russia, and will enable other countries and companies to benefit from the important work being conducted in the country” (8).

Assured of solid funding, the success of biotech investments in Russia lies mostly with effective management in

order to minimise bureaucracy, maximise transparency in public spending and guarantee the protection of intellectual property.

The extent of recent developments in Russia indicates that the country is taking big steps to gain influence within the scientific community and establish itself as a major force in biopharma innovation.

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