Interview with Egor Beketov, CEO, Biopharmaceutical investments of RVC (RVC BioFund)

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Biofund is an independent spin-off of the broader Russian Venture Capital organization. What is the working relationship and synergy between these agencies, and what are the market conditions that have necessitated the creation of Biofund?

Biofund was created on January 24th, 2011. There are two stakeholders in the creation of this company: the RVC, which owns 94% of our equity; and the Venture Innovation Fund (VIF), based in St. Petersburg, which owns the remaining 6%.

As of June 2011, 12 RVC backed funds run a portfolio of 71 companies, invested capital totaling RUB 8.2 bln (~USD 300 mln). Biofund was founded on the model of RVC Seed fund. Amount of the authorized capital of the Fund 1.5 bln RUB (approximately $55Mn).

As the RVC is our majority stakeholder, we consider ourselves a subsidiary of the RVC. In our work, we abide by the principles, and aspire to the goals, set before us by our parent organization. The RVC very actively involves itself in its affiliate funds, instilling them with the best internal and global practices of venture capital investment.

To address the question of the impetus for the creation of our organization, I would say the following. First, it is the demand of the Russian market for new, innovative, biopharmaceutical products. This demand is expressed at the very highest levels—both the president and the prime minister have said that the Russian pharmaceutical industry must undergo modernization, with the

objective of bringing to the market, by 2020, a 50% percentage of innovative domestic medicines.

In connection with this need, several investment companies were created with the participation of RVC capital in 2008 and 2009—Maxwell Biotech Venture Fund, Bioprocess Capital Ventures, etc. It seemed, at first glance, that if government would simply put resources into the hands of investors, the problem would be solved. So why create Biofund, when we already have a number of other investment instruments?.

The problem is that, if we look at the long process of drug development from molecule discovery to market, we note that a team of scientists that discover a potential drug candidate must undergo a host of research work, analytical work, and etc. As a rule, this kind of work is performed under the auspices of third-party services. That is, the team approaches CROs, CMOs, and the like.

Investors that put their capital behind drug development in Russia came across the challenge that high-quality services of this kind do not exist domestically. This is not to say that Russia does not have contract research organizations; nor is this to say that there are no contract manufacturers. However, if we want to develop pharmaceutical products that are world-class, we must develop them in accordance with world standards. For laboratory research, this means GLP; for clinical research, GCP; for manufacturing, GMP.

When we look at the structural framework of drug development in Russia, we see a particularly large gap in GLP certified laboratories. The reason for this is that, today, these services are usually provided by research institutes and universities, and such organizations are not oriented towards commercial gain. Their laboratory practices largely serve academic, internal needs. The drive toward modernization virtually passed them by, because they had no reason to modernize: for internal purposes, the quality of their services is sufficient. Today, Russian regulators accept research dossiers that delineate products developed without accordance with GLP—there is no stimulus to modernize.

The outcome is that most Russian medicines that are developed by academia remain within Russian borders; few markets outside of Russia are interested in dossiers of such quality. This is troubling for investors. Without a doubt, promoters in Russia are interested in the kind of success a blockbuster like Velcade can bring. They would like to find such products in Russia. If a blockbuster drug candidate is discovered, in order not to limit its distribution to the Russian territory only, we must ensure that its entire development schedule is carried out within the frame of international standards.

Currently, these services are for the most part available only outside of our borders. We understand that generally speaking, 50-70% of drug development capital is used to fund services. This means that the majority of drug development capital is being sent abroad. There are two problems with this scenario: first, foreign services are quite certainly more expensive; and second, when money leaves the country, it means lack of internal development.

In 2010, within the structure of the RVC's portfolio and its funds, there were over 20 drug development projects. Therefore, large sums of money were going abroad. In order to curb this situation, Biofund was charged with investing in projects that would stimulate the development of domestic service companies in the biotech sphere.

This is Biofund's primary mission. We aim to create companies and to close the gaps, so that Russia might have high-quality research providers that could work, first, for our domestic companies; and, of course, to be competitively aligned to work for foreign players as well.

What will be the significance of bringing in the resources and expertise of Western technology companies?

This is good question, especially for us. Biofund, as I mentioned, is mostly involved with stimulating the service industry. Further, as I mentioned, high quality service is not readily available in Russia; this means that Russian service companies do not have the competencies for it. Therefore, one of the business models we are implementing is to take the existing infrastructure of the Russian market, and bring in to the Western level.

When I say that existing infrastructure is our foundation, I emphasize that we are not developing anything from scratch. If we find a team with a strong foundational infrastructure that is ready to bring it to a higher level, we consider investing in their project. In other words, we support them through the mechanism of investment.

A strong characteristic of such projects for us is the participation of multinational technology leaders. This participation can take a number of forms. We are not only interested in Western capital but in risk sharing as well. We are much more interested in competency transfer, technology transfer, and management development.

I mention management because the goal of any service company is to sell its services, and the amount of service requests that such a business receives from foreign enterprises is a measure of its success. A key driver in securing such requests is the competence of its management. Management team must understand the frame of working in the West, and how to implement it in

Russia.

One way to acquire quality management is to buy a CEO from abroad. However, this is expensive, and the economy of the project will obviously not gain from such a decision. Instead, we are looking at a number of different options. For example, we are sending top personnel from the teams we want to work with to special training programs. Conversely, we invite specialists to come and train managers locally.

Without a doubt, if we do not have the participation of Western entities, we will not be able to quickly advance this industry.

To truly develop the biotech foundation in Russia, capital investment is only one step. When we spoke to Ms. Victoria Anashkina, head of Amgen Biopharmaceuticals in Russia, she noted that to make the environment attractive for biotech companies, a clear and appealing regulatory system is necessary. What signs are there that the Russian environment is heading in the right direction?

The point here is that we need to harmonize internal standards with international ones. I will again speak about the segment I understand best: GLP. To what extent is GLP harmonization realized in Russia? Efforts to implement this standard, and the advancement of normative documentation to this effect, began in the early 2000s. However, today, as I mentioned, there remains a lack of strict legislation that demands that laboratory research—analytical studies, preclinical studies, etc.—must be up to GLP standard.

A strong signal for the industry would be if the authorities declare that a product will not be allowed onto the market if development was not in accordance with GLP. This will be a great stimulus for the mass modernization of our infrastructure.

This kind of signal has not yet been sent. First of all, work towards harmonization is still underway. But there are positive steps. Just in June this year, a document reached the authorities that outlined the necessity of finalizing this harmonization and implementing this standard. It is clear that legislation is on the horizon.

Biofund, as an investor that is looking into funding GLP-based projects, is pleased with this kind of progression—because it will quite effectively purge from the market any service providers that are not GLP-certified, high-quality organizations.

At the recent BIO International Convention in Washington, Russia had its own pavilion for the first time in 20 years. At the time, Evgeny Kuznetsov, head of development and communications at RVC, said that the time is ripe for Russia to declare itself not only a seller, but also a producer and

developer. Can Russia become globally visible as a biotech destination?

I strongly believe that it can, and it will. The question is only how quickly. The Russian government, as we have mentioned, has declared that by 2020, a significant amount of locally-developed innovative products should permeate the market. These products must furthermore be ready for export.

By 2020, Russia’s positioning amongst nations that conduct R&D and generate intellectual property will be noticeably more pronounced. It is clear that Pharma 2020 is a remarkably multifaceted initiative, which seeks to develop its goals from all relevant angles. Significant resources are being pumped towards the strategy, and towards these various avenues of development. There are investment instruments and grant instruments that are aimed at supporting Russian-born projects in the pharmaceutical sphere.

There is no question that we will achieve our objectives. The issue is only whether it will happen in 2020 or 2021!

How will you measure the success of the Biofund organization over the coming years?

Active investment into service projects is something that we are looking into for the first three years of our existence. During those three years, we would like to invest, as a minimum, into five companies that will be able to fill the service gaps in the country. The market is not quite ready for this level of service infrastructure—especially given the regulatory challenges we have discussed—so five companies is an ambitious goal. If we succeed, we will consider ourselves quite accomplished. We understand that each of these projects will likely involve multinational participation.

The greater goal of the fund is definitely to generate revenue from investment into product development projects, and to participate in the realization of Pharma 2020. In the first three years, we will also invest in five drug development companies. The true measure of our success will therefore be participation in the commercialization of strong, in-demand products, and sharing in that success with those companies who own the intellectual property. We expect to gain a return on investment from the generated revenues.

The process of investing into companies that engage in drug development is quite standard. We understand the path a product must take from drug candidate to market. The key challenge for an investor is to find a team, and to find a candidate that, in our view, would be successful on the market. Once a drug successfully passes the second stage of clinical trials, if the market for that

product is understood, and development of the product was done with high standards, as a rule, big pharma companies get in line to purchase the proven, low-risk asset. The current tendency amongst large pharmaceutical companies is to reduce the amount of self-investment into R&D, and to find more developed products on the open market.

What is your personal mission as head of Biofund?

I have effectively been involved in the sale of pharmaceutical products for the entirety of my professional career. These products have been high-cost, innovative, and, of course, foreign. My greatest ambition is that I could participate in the development of such products at the Russian market. I would like to see Russian drug developers achieve international success. Biofund, and the Pharma 2020 initiative, are means to realize this ambition.

What is your final message to the international readers of Pharmaceutical Executive?

Biofund is looking for reliable partners on its path to modernizing and advancing this industry toward innovation. In turn, we are ourselves reliable partners. We invite collaboration!

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