

Main drivers and constraints for the development of the biotechnology industry

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Abstract. Biotechnology is an industry that continues to attract the attention of both the scientific community and the business sector, and it plays a key role in various aspects of modern society, including medicine, agriculture and industry. This article examines the key drivers and constraints of the biotechnology industry, examining the factors that drive its growth as well as those that pose challenges and obstacles to its growth. Biotechnology is an innovative field that has been successfully applied in various fields, including medicine, agriculture, food processing and the environment. However, despite its enormous potential, the biotechnology industry faces a number of drivers and constraints that may affect its development.

1 Introduction

The integration of high technology into the international market is a significant challenge for Russia. The lack of effective demand for a considerable portion of high-tech products has resulted in a loss of Russia's advanced technological base in fields such as astronautics, aviation, biotechnology, and more [1-2]. To prevent an increasing gap between Russia and developed countries, which is estimated to be about 10-15 years, a key task for the government should be to provide financing and regulation for biotechnological production.

Biotechnology is one of the most rapidly evolving fields in science, industry, and business (fig.1). Breakthroughs made by established companies and emerging startups present promising opportunities for market development [3]. Transitioning from an academic discipline, biotechnology is becoming an effective tool to address global challenges, increasingly becoming part of everyday life. This industry is instrumental in enhancing the overall quality of life, particularly in areas like food security and clean energy production. Over the past decades, biotechnology has evolved into a fully-fledged independent industry that generates innovations in related markets[4].

The industry's untapped potential holds prospects for future progress. It is anticipated that the biotechnology market will soon undergo a reset, resulting in a substantial influx of financial investments [5]. Additionally, the creation of new markets and product niches will encourage the emergence of new companies. Consequently, the modern biotechnology industry is poised to become a primary objective for global superpowers, with success leading to international dominance.

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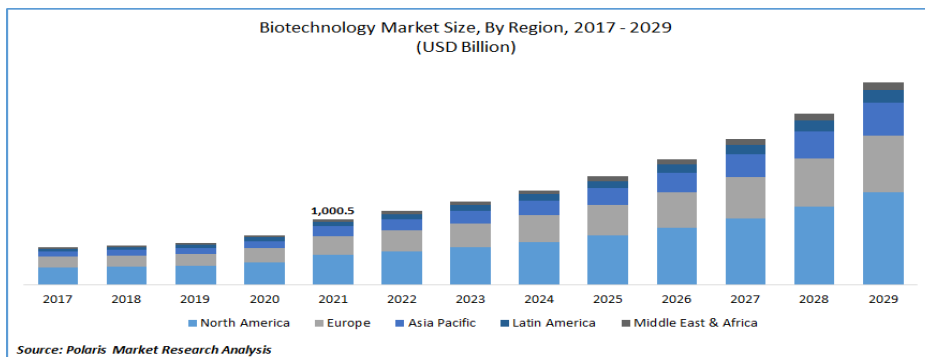


Fig. 1. Global Biotechnology Market Size from 2022 to 2029

Despite the substantial developments in biotechnology, there is a notable lack of comprehensive studies on the market's characteristics and features in foreign and domestic literature. Over the past two decades, biotechnology has seen the emergence of scientific and applied disciplines, including microbiology, cell biophysics, and molecular genetics. However, issues related to market development in these biotechnology areas remain largely unresolved [6]. As a result, the importance of analyzing the current state and future prospects of the biotechnology market continues to grow.

It is crucial to begin by defining the characteristics of the biotechnology market and recognizing its unique attributes. The next step involves conducting a comprehensive study of biotechnology companies to understand the characteristics of their development and analyze the challenges they face in their business activities. Notably, such studies are scarce in Russia, and often they only address specific aspects of the research tasks outlined here.

For instance, S. Mikhnevich's work focuses on the regulation of trade in genetically modified products, primarily based on the principles of equivalence and precaution [7]. Existing works dedicated to the production of biotechnological products often provide a narrow, localized view of their subject matter. Thus, the Russian economic literature exhibits a notable absence of comprehensive exploration of the biotechnology market and its international economic development aspects, both within Russia and on the global stage.

2 Research Methodology

At present the Russian biotechnology market is in its early development stage (see fig.2). According to the data, an important proportion of products in different categories are imported. Russian companies are primarily focused on creating biosimilars in the primary segment, which involves biological products. It is partly due to the state's policy of promoting import substitution in this sector. This emphasis is partly attributed to the state's policy of promoting import substitution in this sector [8]. Moreover, the system for effectively commercializing innovative concepts and breakthroughs is in need of substantial development. Innovative research activities are somewhat limiting on scale, and the systems for effectively commercializing innovative concepts and breakthroughs are in need of greater improvement.

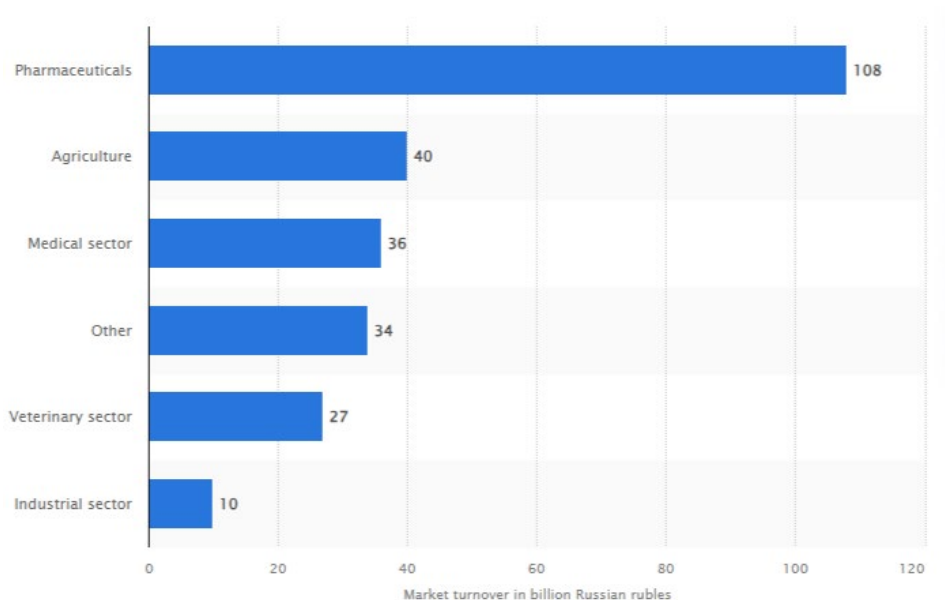


Fig. 2. Biotech market revenue by sector Russia

In addition, Russian biotechnology companies face financial constraints, primarily because they concentrate on serving the domestic market, but also in fact products of them do not have high competitiveness on the global stage [9]. Large international companies receive a large part of the profit from domestic and global market, allowing them to allocate up to 15% of their own capital for research and development activities. In contrast, large international companies derives a significant portion of its revenue from outside markets, allowing them to allocate up to 15% of their income to research and development activities.

To achieve this, the relevant government departments are actively working on new legislative reforms, the introduction of new standards and regulatory requirements for biotechnological products. The development of innovations in technology facilities is carried out by creating an innovation environment, the introduction of new industry support mechanisms, and launches pilot projects towards it in the field of biotechnology.

3 Results and Discussions

The drivers and limitations of the biotechnology industry can be summarized as follows:

Drivers [10].

1. Government Funding: Increased government spending on expensive drugs through programs like additional drug supply (ADS) and support for biotechnological import substitution.

2. Cluster Policy: Promotion of business integration and attracting foreign investments through regional clusters.

3. Investment from Development Institutions: Funding from development institutions to support young innovative companies and facilitate the transfer of foreign technologies.

4. Vaccination Programs: Expansion of the national vaccination schedule, driving growth in the vaccine market.

5. Preventive Medicine: Focus on preventive medicine leads to increased demand for laboratory diagnostics and innovative diagnostic systems.

6. **Surgical Interventions:** Growing numbers of surgical procedures create demand for medical products made from biocompatible and biodegradable materials.

7. **Information Technology:** The well-developed domestic IT industry can enhance the competitiveness of the Russian bioinformatics market.

8. **Agricultural Development:** Intensive agricultural development boosts the consumption of immunobiological products, feed additives, and waste management.

9. **Import Substitution:** Continued potential for import substitution in biopharmaceuticals, industrial biotechnologies, and agrobiotechnologies.

Limitations [11].

1. **Unfavorable Macroeconomic and Political Situation:** Economic and political challenges create risks for investment projects in Russia.

2. **Outdated Industrial Base:** Outdated facilities and a lack of GMP certification limit the production of innovative drugs for foreign markets.

3. **High Import Dependency:** Reliance on imports, especially for biotechnological substances, poses a limitation.

4. **Lack of Qualified Personnel:** Insufficient skilled workforce and modern educational programs hinder biotechnology adoption in existing industries.

5. **R&D Funding Shortage:** A significant lack of funding for research and development, particularly for RAS divisions.

6. **Inadequate R&D Support Programs:** Incomplete government support programs hinder the commercialization and industrial production of new products.

7. **Unclear Regulations:** Uncertain localization rules, lack of standards, and technical regulations impede the development of certain biotechnology segments.

8. **Lack of Government Incentives:** Absence of government incentives for biotechnology use in areas like energy and agriculture.

9. **Non-transparent Procurement Mechanism:** Lack of transparency in public procurement and guaranteed sales hampers private investments in developments.

10. **Venture Capital Bias:** A preference for information technology in venture capital markets, with limited investment in biotechnology.

11. **Logistics Challenges:** High logistics costs and underdeveloped customs regulations delay the timely delivery of equipment, materials, and reagents.

These factors collectively influence the development and growth of the biotechnology industry in Russia.

4 Conclusions

The Russian biotechnology sector receives substantial support through state programs and federal target programs (FTP). These initiatives are coordinated by relevant ministries and departments.

To foster innovation and provide financial resources to promising high-tech companies, various institutions collaborate in Russia. Notable among these is the Fund for Assistance to the Development of Small Innovative Enterprises in the Scientific and Technical Sphere, often known as the Innovation Promotion Fund. The Skolkovo Foundation, regional funds, private investment companies, and venture funds also contribute to this support ecosystem. These organizations offer financing, mentorship, and networking opportunities to emerging high-tech companies, including those in the biotechnology sector.

To further stimulate the growth of high-tech enterprises, including those in the biotechnology market, Russia has established a network of technology parks and technopolises. These centers provide innovative companies with a range of support services, including access to advanced research equipment, facilities for producing trial product batches, service infrastructure, consulting, and certain financial incentives.

Additionally, Russia has established five technological special economic zones (SEZs), which offer a package of customs and tax preferences to developers and manufacturers of high-tech products. These SEZs create a favorable environment for high-tech businesses to operate and expand.

Moreover, Russia has been actively developing elements of the venture investment market to encourage investment in biotech start-ups. This growth in high-risk investments can significantly support the development of the biotechnology sector in the country.

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