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**Specifics of business model for innovative product in biotech sector in Russia**

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Application for self-completion of course work.

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# Introduction

In today's world, the knowledge and use of business models is expanding. This is justified by the business need for a holistic approach and analysis of its activities, especially at the stages of the company's inception. This paper presents an innovative approach to creating a business plan, the approach is tested on the creation of a real startup, which received a grant from St. Petersburg University for implementation.

But what is at the heart of the business model? What are its core stones?

The goal of this paper is to *identify key features of business models in biotech sector to consider for startups.*

In accordance with the goal of this paper, the following work tasks were formulated:

* define goals and types of business model
* find the features of a business model for startups
* study the features of the biotech industry in Russia
* create a business model that takes into account the specifics of the biotech industry in Russia
* apply this business model at the real startup

It is also worth noting that the company has not yet entered the market, that is, it exists in the status of a startup. Accordingly, the elements of the strategy presented below will be the only one at the moment consistent action plan for making any management decisions in the company.

In order to make all decisions on the development of a business plan and, in particular, drawing up a business canvas, essential and justified, the following methods of collecting primary and secondary information were used:

1. Survey of a potential target segment in the format of in-depth interviews;
2. Analysis of secondary information, in particular literature on business model development.

As a result of this work, practical recommendations were formulated for building business models in the field of biotech for making management decisions by the founders of the company at the stage of business formation, as well as recommendations for using this model.

# The structure of the work reflects the logic of the entire study and is consistent with the stated objectives:

# The first chapter analyzes the existing business models, identifies the goals and types of the business model, and also identifies the features of business models for startups.

# In the second chapter, I analyzed the features of the biotech industry and tried to create a business model for biotech companies in Russia based on the identified features.

# The third chapter presents the application of the business model in the Light Up startup, the third chapter is the business plan prepared for the SPbU start-up competition.

# In conclusion of this work, the main results obtained in the course of the study and conclusions on achieving this goal are presented.

# Chapter 1. Approaches in business models.

## 1.1 Definition of business model

The first articles on business models appeared in the 1990s, but important and intensive research began only in the 21st century, in particular, the number of articles in databases increased more than 12 times. Now more than 2000 articles are published on this topic a year, so let's look at the main chronology.

To analyze all the research on business models, I used the most cited articles in google scholar and magazines on this topic in recent years.

The business modeling articles I study are based on empirical research or case studies. This means that the business model is part of business practice and requires more understanding and generalization.

Deputy forensic interpretation, relevant to the concept, since most of them contain more transparent documents than perspectives. Understanding the main task involves answering three questions:

1. What are the key points in the implementation of the business plan?

2. What can we do to make money on its products?

3. How to make company interesting for investors?

These questions are asked to understand the financial model and the market positioning model. To understand the value of a business and find resources.

Lazonick W. research has highlighted differences in understanding of the relationship between interpretations. [[1]](#footnote-1) This is crystal clear: there is a time to mix the inner wisdom of the business its external environment, helped to define and achieve growth goals.[[2]](#footnote-2)

Teece was the first to mention business modeling, and he developed a classification scheme for e-commerce business models. Malthora then examined the company's knowledge management systems and emphasized that constant changes in the external environment train the organization's need for a model for collecting and processing information. Dubosson-Tourbay then proposed a theoretical framework for e-business business models and created schemas for classifying business models.[[3]](#footnote-3) Magretta then defined the business model and analyzed the differences from the company's strategy. Osterwalder at the beginning of the 21st century formulated the key elements of the business model structure. Morris then deduced the following elements: value, market, firm identity, competitive strategy, finance, and the company's growth model. Osterwalder then proposed a business model outline. Teece has identified its importance in the financial and organizational structure of the enterprise. Next, we will consider such an element as risks.[[4]](#footnote-4)

Aarøen, C., & Selart, M. in their article, consider risks as an element of a business model, based on the consideration of external factors affecting the company. In the future, we will consider the risks that are specific to the biotech industry and, based on them, we will draw up a new outline of the business model.[[5]](#footnote-5)

## 1.2 Limitations of business models

Intermediate access points to close any alliance between the BM for defining a single market.

But if he gives a detailed model of the unity nibh. Hence he sets down the face of battle is in the analysis and in the lowland also, and the BM is, in the relationship, ie, that it acts as a unity of analysis. They could provide, without prejudice to the stability of the firmness of, or permanent assembly, in the mass of. If the analysis is based on the company's involvement in a war with each other, the implementation of this measure, with the market for the new building, to require hosts come in, the affairs of the modification of existing networks, and through this, changes in the company's of the woman. You will need to understand that as companies in different areas, grade equipment, and goods and liabilities, competition, etc.

For example, a leading company in the region to begin a new business model. At the same time, some kind of middle-owned enterprises to adapt to the existing marketing tools. It is understandable that a number of different in different societies, and the other connection is made between the model and the business of war would be his. In addition, a network of a society, which deals with the business in the market; builds the hindmost as they had appeared, and the other plane is that at the time of war, beginning at a certain place, they were not, but to the network.

In summary, for determining the level of business development and market behavior analysis, which allow its competitors to resolve past disagreements about the relationship between our business model and the reasons for the war find their merits[[6]](#footnote-6)

Since the mid-2000s, the authors have been trying to generalize, including creating a general BM construction outside of industry specifications, significantly extending the scope of the BM usage problem and avoiding the exclusive use of the term to analyze the operation of companies. in the field of "e-commerce".

When studying BM in the context of networks and partnerships, the authors emphasize that value creation can no longer be considered within one company, value is a product of the interaction of different actors within the network. This evolution in the understanding of value creation requires a revision of the concepts associated with it (Nenonen, Storbacka, 2019). Another important area of research is the impact of BM on company performance).[[7]](#footnote-7) Taking into account the previously considered BM research and identification habits no longer apply to BM for the following reason.

1. Confidence combines the definition of a business model: the definition is about creating and delivering value to the consumer, doing everything possible in terms of sales revenue. For example, the section does not depend on the analysis reflected in the structure of the company, and only once at the same time your amount prays for the birth, orders and removes the premium price from the sale after the corresponding order.

2. Consider Marcus in a broader context, taking into account all ages and categories of all participants in the chain of events.

3. Use a lot of information to access various components that don't make sense in technical management, marketing, performance management, innovation management, depth, BM.

4. Use the web as a theme to create and spread the value of your fears, to reunite and individually change network members.

The issue is considered step by step, one by one, and is decided by the former action council.

For example, at the exhibition of BM, one after another, he determined the core of the BM ratio in the stone structure of the so-called building.

I propose a model of thinking that will focus on space and show how different parts interact, as it was done earlier using the author's method.

## 1.3 Features of business models of startups in the early stages.

Ries's theory has adapted the ideas of the concepts of lean manufacturing and the resulting concept of lean consumption for startups.

As a reminder, lean production (lean manufacturing) is a management concept based on an unswerving commitment to eliminating all types of waste and maximizing customer focus. In short, a company must produce:

- what the client wants

- when he wants it

- in the amount that he requests

- at the price that suits him

- so high quality as to satisfy his expectations.[[8]](#footnote-8)

As we can see, the focus of the concept is on the consumer, his expectations and impressions from interacting with the company.

Using Stephen Blank's methodology allows the company to iteratively work with consumers to formulate various hypotheses and test them, while Agile methods allow you to iteratively develop and test a product, first of all implementing the functions most demanded by consumers. Therefore, the combination of iterations of both concepts seems to be quite organic. As Steve Blank notes, the Lean Startup concept can significantly reduce the risks of starting a new venture: “According to it, experimentation is preferable to a detailed plan, studying consumer feedback on a startup product is preferable to intuition, and product development in short cycles (iterations) is preferable following a prepared plan”.[[9]](#footnote-9)

The third source and part of the Lean Startup is the prototype business model. As in the case of a regular startup, Steve Blank recommends using Osterwalder and Pignet's canvas, while Ash Maurya's canvas of the lean startup business model, described in his book Running Lean, is the most popular. The model was named Lean Canvas and included nine components: Customer Segments and Channels, Problem and Solution, Unique Value Unique Value Proposition, Unfair Advantage, Key Metrics, Cost Structure, and Revenue Streams.[[10]](#footnote-10)

As we can see, compared to the author's template for a traditional startup business model discussed earlier, Maurya made very few changes. For example, in the structure of the canvas, three elements (subcomponents) were identified, which are sometimes considered by some followers as independent components. Thus, the “Problem” component included the “Exiting Alternatives” subcomponent, similar to the component of the same name in Brian Gladstein's business model canvas.

# 1.4. Key features of biotech industry in Russia

Medical biotechnology includes the development and production of biotechnological products for the diagnosis of human diseases, their treatment and prevention of the harmful effects of environmental factors on human health. The program provides for a set of measures for the creation of modern diagnostic tools (biochips, biosensors), biocompatible materials and the formation of personalized medicine, which are based on systems biology, post-genomic technologies and bioinformatics, as well as measures for the development of cell technologies.[[11]](#footnote-11)

Based on the analysis of the development of the world market at the moment, it is possible to identify several of the most important areas of research and production that form the basis of medical biotechnology of the future.

A trading system is a system that takes different areas under different conditions because it requires the use of different methods for different industrial success machines because of the commercial and banking environment in the region or country today. Currently, all the provisions of this article are to prepare for biological research, the development of professional technicians in the industry. At the end of the twentieth century and the beginning of the 21st century, almost every country in the world focused on the complex development of biotechnology. The main reason for combating this application is related to agriculture, light industry and energy. In general, infectious diseases develop in the war against the oncology engineer. But more important is the use of biology and medical treatment. Beginning in the mid-1990s, when they began to supply a significant portion of the pharmaceutical industry, pharmaceutical companies began to engage with serious biological companies. This is for many reasons:

* slowing down of technological progress in pharmaceuticals;
* limited duration of patents for pharmaceutical products;
* growing competitive pressure from imitation companies from India, China, Poland and other countries;
* in the presence of the three previous factors, there was a glut of related industries - chemical and pharmaceutical financial capital.

And as a result, "squeezing out financial capital" into the biotechnology industry. At the same time, the negative income of the industry did not become an obstacle to its capital inflow.

1. The most important factor for the development of commercial biotechnology is entrepreneurship as a flexible and dynamic source of innovation and commercialization. But the re-creation of an innovative and entrepreneurial environment, similar to the one that formed in the United States (California), which makes it possible to "pull" the unprofitable biotechnology industry, is possible only if there is an excess of financial capital in related industries and throughout the economy, allowing the industry to have debts deferred for the future with negative profit. In this case, a surplus of capital has formed in the pharmaceutical industry.

2. A very serious problem in the development of biotechnological companies is the compliance with international standards of development, production and, in particular, clinical trials.

 3. The innovation component is less significant due to the free distribution of patents, licenses and technologies. But such a state has developed in the USA and some European countries due to the appearance of a large number of developments that have not been brought to the market.

4. Biopharmaceutical clusters that have emerged in the world have formed serious barriers for new companies in the biotechnology and pharmaceutical markets. At the same time, the possibility of artificial reconstruction of such clusters is questionable.

5. Clustering for biotechnology can be divided into two types - local for small and medium-sized biotechnology and large biotech pharmaceutical companies and global for large medium-sized biotechnology and pharmaceuticals, which provides certain opportunities for the development of biotechnology at the regional level.

Russia has all the necessary capabilities and resources to become one of the countries actively developing biotechnology. This is facilitated by a high educational, scientific and technological potential, as well as the availability of appropriate raw materials, which are currently not fully utilized. There is no doubt that the development of biotechnology should become one of the priorities of state policy[[12]](#footnote-12)

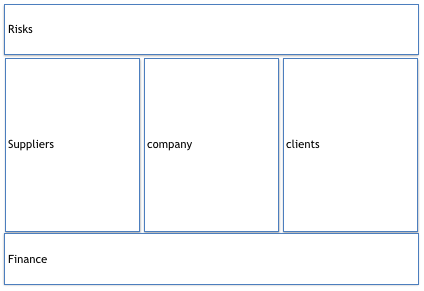
# Chapter 2. Creation of a concept of business model canvas for biotech

As described in the previous chapter, the following characteristics can be distinguished for biotech companies:

1. High level of risks to be considered.
2. Entrepreneurship and willingness to take responsibility for the product being manufactured.
3. Project team. It is important that the team is ready to modify the technology in accordance with market requirements and that the original composition remains.
4. Ability to comply with international standards in development, production and clinical trials.
5. At the regional level, the innovation component is less important, as patents, licenses and technologies are often freely available. However, for startups, the new development provides an opportunity to be the first to gain significant market share.
6. It is important to have pre-clinical and clinical trials in order to justify the possibility of selling the product.
7. In the monetization scheme, it is necessary to take into account the possibility of earning money on licenses
8. The specifics of selling products in the conditions of Russian realities. Most of the sales are direct, the role of marketing drops significantly, as the emphasis is on existing technology.

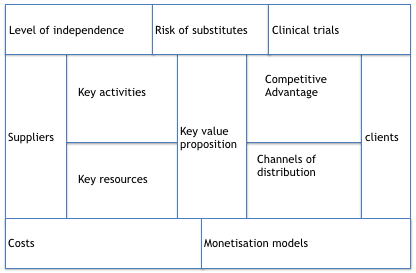
Also, in biotech projects, it is necessary to take into account the risks, which mainly consist in unsuccessful clinical trials, sub-institutes and dependence on suppliers.

Given these features of the biotech industry, I propose the following business model based on the analysis of business model variations.



*Table 1. Business model canvas with risks*

As we learned in the previous chapters, the business model takes into account the processes above. So the outline of Osterwalder's business model was drawn up. In my model, I propose to add risk accounting, which is related to partners, company value and customers. Risks are located above these sections, respectively.



*Table 2. New business model canvas*

The proposed business model is based on the process of defining, offering and creating value for the company's customers, then the monetization process, which can be varied depending on the chosen model. The business model is an independent unit of analysis and demonstrates a certain structure of interacting elements.[[13]](#footnote-13)

This model demonstrates the value chain in a company.

The difference between the canvas above is not only in the industry specificity of biotech projects, but also in a more rigorous numerical formalization, which helps to quantitatively compare the business canvas of one biotech project with another, which helps investors make decisions on the pitch faster and more efficiently.

Another difference of the proposed canvas is the replacement of customer relations with a competitive advantage of the company[[14]](#footnote-14). This is also justified by the specifics of the biotech industry, where direct sales are mainly carried out.

# Chapter 3. Business plan

# 4.1 Summary

About 6 million new cases of cancer are registered in the world every year, in Russia with a population of 144 million - 0.5 million cases

Objective: early diagnosis of tumors

The use of methods of fluorescence biomedical diagnostics will make it possible to find 100 times faster and more efficiently.

Problem: Light passing through biological tissues is scattered. It is impossible to directly see the outline of the luminous area, especially if it is located at a considerable depth.

1. Work on the red border of the spectrum - the area of ​​transparency of biological tissues;

2. Use of plasmonic nanoparticles - amplification of the analytical signal by 104-108 times

Own production of tags is planned for 3 years of operation, but so far the substances for synthesis are purchased from suppliers.

The investment costs required for the implementation of our project are 3,214,224 rubles. We plan to have a net present value of 24.2 million and an internal rate of return of 54.18%.

# 4.2 Business description and market analysis

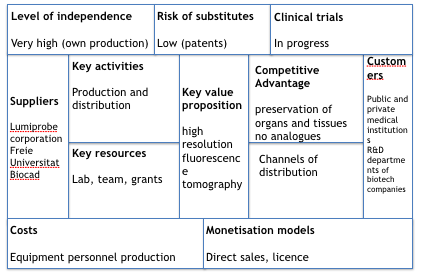
**Business idea**

Development of nanocomposite fluorescent labels for selective detection of ultra-low concentrations of biological objects in vitro and in vivo. The obtained labels can be used for sensitive localization of tumors, studies of metabolism, pharmacokinetics of substances, imaging of structures of organs and tumors, detection of ultra-low concentrations of substances in the transparency region of biological tissues.

**Business concept**

The company specializes in the sale of a substance containing fluorescent labels that can diagnose the location of cancerous tumors. Thanks to the amplification of the signal, the doctor gets bionic vision and sees the exact location of the tumor. The development of our own prototypes, the maximum implementation of domestic components and the use of equipment from the Resource Centers of St. Petersburg State University (RC of St. Petersburg State University) will significantly reduce production costs.

**Business model canvas**



*Table 3. New business model canvas*

**Market analysis and major players**

Overseas biotech companies and health ministries see potential:

Johnson & Johnson invested $ 40 million in this research in 2018, in conjunction with FDA grant support.

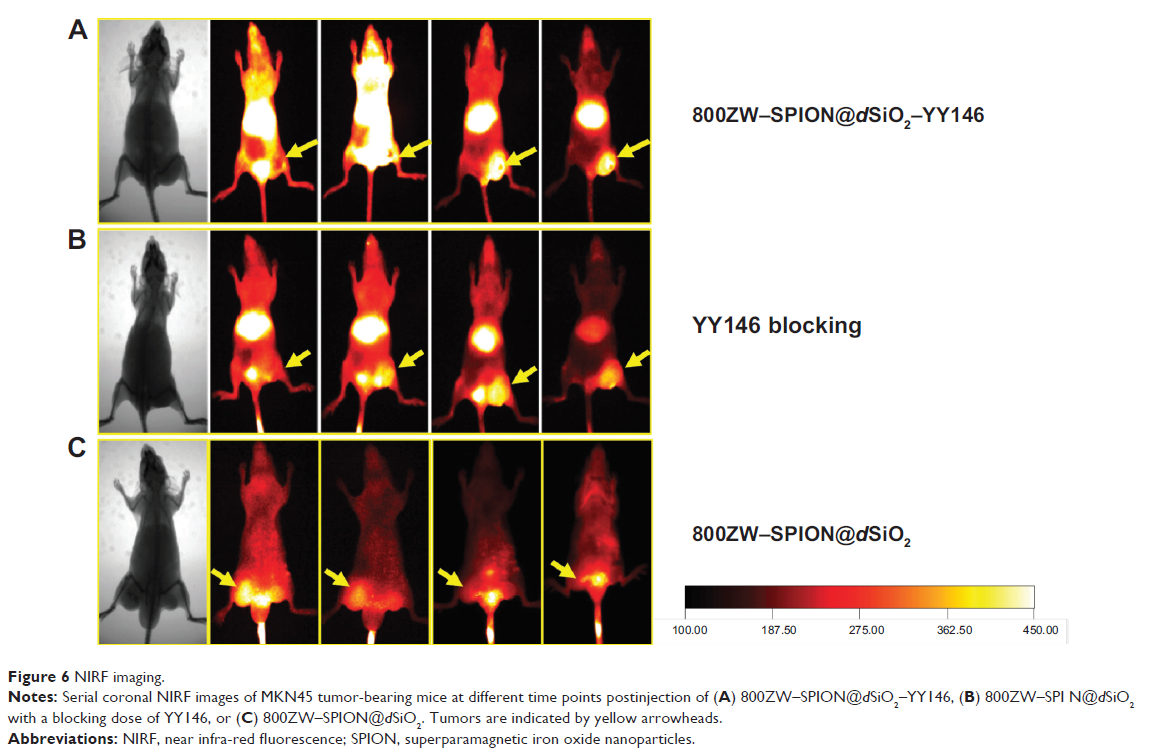


Figure N. Visualization of cancers using iron oxide nanoparticles

The search for patented analogues did not reveal the presence of any developments close to the present project. Related developments of fluorescent labels based on plasmon signal amplification are presented in some publications of foreign scientific groups and are positioned as potentially suitable for thin-layer ex vivo laboratory studies[[15]](#footnote-15), as well as for DNA analysis.[[16]](#footnote-16) So far, these developments remain the subject of only academic interest. In any case, their area of ​​action is limited to the middle band of the visible spectrum, outside the red border, so they cannot be used either for three-dimensional mapping of objects deep in biological tissues, or for express analysis during surgical intervention. Colleagues from the University of Washington in St. Louis used antibody-labeled gold nanorods coated on filter paper to determine cancer biomarkers. This development is fundamentally the closest, but it is positioned as an analytical solution for working with pure cells in vitro due to registration of the characteristic contour of giant Raman scattering (the method is very demanding on the purity of the analyte), and not an amplified signal of a fluorophore conjugated with a nanoparticle, as is proposed in the present project (in whose signal at the border of the red visible area nothing interferes and can be observed with the naked eye). From the point of view of the project, the cited sources prove the practical feasibility of stable modification of particles with antibodies, as well as the effective labels modified in this way with biomarkers of cancer cells.[[17]](#footnote-17)

After cardiovascular disease, cancer is the second leading cause of death in the world. Until the middle of the twentieth century, the only method of treating malignant tumors was surgery, which made it possible to cure people with an early stage of cancer development. But she did not help everyone, people with distant metastases were doomed.

2018 Nobel Prize: How to distinguish between healthy cells and help the immune system attack cancer cells without attacking healthy ones.

A quarter of the drugs currently approved in the States are anti-cancer drugs.

***About diagnostics:*** there are screening tests - mammography, gynecological tests, colonoscopy and an analysis for occult blood in the stool. However, unfortunately, some cancers are still almost impossible to detect in the early stages because they are asymptomatic for a long time - for example, lung cancer or pancreatic cancer.

Genetic testing technologies are developing very rapidly, already in the medium term we will all be making one genetic text, and we will have it for the rest of our lives. So far, there are very few cancers that can be detected in this way, where there are relevant genetic changes. This test is not a prediction, but a serious enough probability that can be prevented. In general, there is very little chance of preventing cancer. Now the topic of liquid biopsy - blood tests - is actively developing. As it turned out, any cancer, including brain cancer, releases cells into the blood: there you can catch a cancer cell and do its sequencing. They can be disassembled today with the help of current technologies: which cell is normal and which is cancerous. Unfortunately, there is no magic wand that allows us to scan the entire body and identify the place where the tumor is in a phase early enough that it helps more than harm.

In Russia, at least, diagnostics are improving significantly. And when we talk about the fact that cancer mortality is periodically increasing in Russia, perhaps this is due precisely to the fact that cancer is better diagnosed. Unfortunately, it is diagnosed, as a rule, in the later phases, and there is a huge difference with Western Europe and the United States.

The Zebra AI algorithm (https://www.zebra-med.com/), used by radiologists as a desktop helper, is more likely to recognize breast cancer (92% of cases) than a technician using automatic detection software tumors (82% accuracy). We are talking about tens of thousands of lives: according to statistics from the World Health Organization, breast cancer - one of the most common cancers - will cause the death of 627 thousand people by the end of 2018.

A technology similar to the Zebra algorithm is currently being tested in the field of diagnosing melanoma, one of the most dangerous cancers. In May 2018, a team of American, German and French scientists led by Professor Holger Hensle from Heidelberg announced successful trials of a development based on the CNN (Convolutional Neural Network) mechanism - that is, on the same technology that is used, for example, to recognize a human faces. This computer program, tested on 100,000 photographs of melanoma, was able to diagnose skin cancer 8% more accurately than a team of 58 doctors: 95 versus 87% of cases.

If in 2012, early stages of cancer were detected in 50%, then in 2017 it was already in almost 56% of cases.

**About treatment**

Comprehensive inpatient treatment at N.N. N.N. Petrova includes the following directions (the same directions in other main medical institutions of our country):

* Radiation therapy
* Chemotherapy
* Surgical interventions for malignant, benign neoplasms and if they are suspected
* Complex cases of invasive diagnostic interventions requiring hospitalization and dynamic monitoring in a hospital setting
* Symptomatic treatment for malignant neoplasms requiring hospitalization

Everything that appears new complements the old: it cannot be said that something new has appeared, and everything that was before has become irrelevant. For example, 50% of cancer patients use radiotherapy during treatment. Here, too, there is progress: less invasive methods are emerging. For example, now proton therapy has appeared. One unit costs 50 million dollars, which will treat several thousand people a year. Such a private center has emerged in Russia. In chemotherapy, various delivery vehicles, nanoplatforms, are emerging to deliver the drug exactly where it is needed. In recent years, immuno-oncology, gene therapy, virotherapy have emerged. Brand new modalities are emerging that promise to potentially cure cancer.

But if we are talking about immuno-oncology, then the fundamental difference with chemotherapy is that the body trains, remembers the cancer, and in case of a relapse it will be able to cope with it itself. Immuno-oncology is an interesting field that can significantly prolong people's lives. Many tumors are difficult to treat precisely because they are able to disguise themselves from immune cells, and sometimes inactivate them. Therefore, the standard methods of cancer treatment used in clinics - surgery, chemotherapy, radiation therapy, hormone therapy - are left without support from the patient's immune system. However, in the oncoimmunology laboratory, a way was found to "restart" the patient's immunity, having previously adjusted it to a specific tumor. For this, dendritic cells from the bone marrow are used (they are always present in the blood along with leukocytes, lymphocytes and other cells), the task of which is to present the main protective cells of the body - T-lymphocytes - with protein molecules characteristic of a tumor (antigens). The process takes place in a special vessel, where prepared blood, previously taken from the patient, is placed, as well as "fragments" of a tumor isolated from his own body, or antigens of a similar tumor available in the bank of the National Medical Research Center. Dendritic cells settle on the walls of the vessel and begin to actively absorb (phagocytose) tumor particles, forming a specific "learning signal" on their surface. With the subsequent introduction of a suspension containing such dendritic cells into the body, T-lymphocytes are able to "recognize" the tumor and start attacking it. The mortality rate is constantly decreasing. In the United States, cancer deaths are declining by 1.5–2% per year. True, for lung and breast cancers it really decreases, while for brain and liver cancers, on the contrary, it increases. The likelihood of a cure depends on the stage at which the cancer is found. Early diagnosis is an important way to reduce mortality. Primary cancer is indeed treatable. Breast cancer in the United States is cured in 90% of cases. In Russia, this is still only 70%.[[18]](#footnote-18)

HIPEC therapy, in which chemotherapy is sprayed with high pressure. This method is used, for example, in the case of a disseminated process (spread of metastases) in the abdominal cavity.

Now 90% of innovative drugs come from abroad. This is not some kind of conspiracy against Russia, but an objective reality. 50% of drugs are developed in the United States, another 40% in Europe and 10% in Japan. In Russia, drugs that would be recognized all over the world are not yet being developed.

Scientists from the Kabardino-Balkarian Republic (KBR) have created material to reduce the effect of chemistry on organs in the treatment of oncology. This is reported by TASS with reference to the head of the Center for Progressive Materials and Additive Technologies of the Kabardino-Balkarian State University (KBSU), Vice-Rector for Science Svetlana Khashirova. According to her, it is a multifunctional polymer nanomaterial - a non-toxic white powder that dissolves easily in water or saline solution, which can minimize the effects of chemistry on healthy organs in the treatment of cancer. The new material will maximize the concentration of the entire dose of the drug on the diseased organ. The material is a polymer nanocomposite, which, upon entering the body, is able to concentrate in certain organs and carry medications on itself. The composite can be used as a carrier that will deliver drugs to diseased organs and help in cancer treatment. The impact on the diseased organ will increase, and the body will suffer less from the effects of chemotherapy. "So far, few polymer materials are known that are of real interest for practical medicine. This composite is able to stay in the body for a long time, gradually giving the drug to the target cell.

Federal High-Tech Center for Medical Radiology of the Federal Medical and Biological Agency (FMBA) (located in Dimitrovgrad, Ulyanovsk region). The center has a radiology building with three X-ray accelerators. All of them are of different power and for different types of tumors - from subcutaneous to deeply located. There is a radiosurgical building, a polyclinic equipped with the latest equipment, and a building for patient rehabilitation. A completed case of treating one person with a proton accelerator costs, for example, about two million rubles. One such accelerator is designed for 50 years of efficient operation. The proton accelerator itself costs about 6 billion rubles. There is also ORNT - this is when the treatment takes place with a radioactive drug, for example, iodine (for thyroid cancer), which a person drinks, or they put it in the form of rods for a person, this is already a method of brachiotherapy (in case of prostate cancer, more than a hundred micro rods are inserted into it, soaked in radioactive material).

**Testing stage**

CAR T-cell technology. Its meaning is as follows: we take blood from a patient, isolate lymphocytes (cells of the immune system) from it and artificially improve these cells in the laboratory, supplying them with the necessary weapon against the cancer antigen, and then pouring them back into the patient's blood. In this way, we arm our own immune systems to fight cancer.

Petersburg scientists have developed a unique device for non-invasive cancer treatment - an X-ray emitter, which acts on infected cells in a targeted manner. This is a joint work of specialists from the St. Petersburg State Electrotechnical University, Research Institute of Robotics, Clinical Hospital No. 122 named after V.I. L.G. Sokolov. The device was first demonstrated to the head of the Federal Medical and Biological Agency of Russia, Veronika Skvortsova. Its uniqueness is that the device can be used immediately during the operation. Through a small incision in the patient's body, the surgeon can combine the removal of the malignant tumor and radiation therapy of the surrounding tissue. Scientists are confident that in this way the time after the operation will not be lost, during which potential tumor cells could gain a foothold in healthy tissues.

Method of preparation for surgical treatment due to superselective endovascular chemotherapy. For a long time, cardiologists have been using an angiograph to expand the vessel. Today, these devices are also used in cancer centers in order, on the contrary, to reduce their diameter or completely close them in order to stop the blood flow to the tumor. Moreover, using this technique, it is possible to target a chemotherapeutic drug that will irrigate the tumor through endovascular delivery. For this technique, we are currently developing the production of a drug based on yttrium. It is very effective in treating liver cancer. In Australia, this drug is already in production, we are simultaneously making our own.

**At the stage of development**

The international scientific group included researchers from St. Petersburg State University, the Center for Medicinal Chemistry of Togliatti State University, as well as the Braunschweig Technical University. The results of the study are published in the New Journal Chemistry. The essence of the study is that scientists have synthesized palladium complexes with acyclic diaminocarbene ligands; this is a new class of compounds. Platinum compounds are now used in the treatment of oncological diseases. But platinum dissolves poorly, and the drugs themselves are toxic. Side effects significantly reduce the effectiveness of treatment. The researchers compared how platinum and palladium compounds behave on breast and colon cancer cells. Both drugs were effective against diseased cells, but palladium compounds showed less toxicity.

**Competitive advantages**

There are no direct analogues of the development according to the principle of action, a similar technique is fluorescence molecular tomography - it uses molecular fluorophores - molecules that emit light at a certain wavelength, combined with antibodies to detect cancerous tumors. This technique has appeared over the past 10 years and is only entering medical practice.

The intensity of the optical signal of nanocomposite fluorescent labels will be several orders of magnitude higher than the intensity of molecular ones, allowing the detection of small objects with high resolution in vivo and ex vivo analysis, or the analyte at low concentrations in laboratory in vitro analysis.

The study of biological objects by optical methods in vitro, and especially in vivo, is difficult in a wide spectral range, since a large amount of organic substances interfere with the luminescence spectra, which are extremely difficult to compensate. However, there are methods for the synthesis of nanoparticles of a specific shape (nanorods and nanobipyramids), which are active at the red border of the visible spectrum and in the near infrared region. This range is not absorbed by biological tissue, i.e. passes through, allowing you to see the object inside the organ.[[19]](#footnote-19)

The cost of our labels with significantly better sensitivity indicators (up to 10-5) in comparison with molecular labeled fluorophores will be comparable or lower than existing analogues. At the first, the purchase of fluorophores for modifying nanoparticles with a resonant optical region will be carried out according to the commercial proposals of existing manufacturers. However, the working concentration the obtained labels will be orders of magnitude lower than the working concentration of molecular fluorophores, thus, the slightly higher real cost of “one” label will be leveled. The supplying companies on the market belong to foreign companies, which increases the cost of the product. After the start of the successful sale of the first stage product it is planned to establish the synthesis of its own fluorophore molecules for medical purposes, especially since there are no such manufacturing companies in Russia, and the synthesis of these compounds is not difficult.[[20]](#footnote-20)

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter | Product being created | Cy5 Phoenix Pharm conjugates. | Cy5 conjugates |
| Volume (concentration) | 100 µl (1 µg / mL) | 100 µl (1 µg / mL) | Sigma-Aldrich (Merck) |
| Availability | Russia | Import (USA) | 100 µg |
| Comparative signal strength | 1 \* 104-108 | 1-2 months, extra charge | Import (USA) |
| The cost | $ 213.2 | 1 | 1-2 months, extra charge |
| Producing country | Russia | 513 $ | one |

There are no direct analogues, in Russia we are creating a market

**Key differences**

**Purpose of the product**

Fluorescence molecular tomography is the latest medical imaging technique that is rapidly gaining popularity in clinical practice. Academic interest in the development of molecular fluorophores is increasing every year.

This approach uses fluorescent dyes - labels modified in such a way as to selectively bind to cancer cells that are safe for metabolism. The patient is injected with labels into the bloodstream, after which, due to their structure, they "stick around" cancerous tumors, and, under the influence of light, literally illuminate the desired areas during diagnosis or direct surgical intervention.

In medical practice, this approach is still only experimental, but has already managed to prove its effectiveness. Biotech companies and health departments see great potential in this research: Johnson & Johnson invested $ 40 million in research in 2018, in conjunction with FDA grant support

Every year hundreds of thousands of people around the world undergo surgeries to remove suspicious tumors and blemishes. Often the entire suspected organ is removed, for example, when it comes to the lungs. Fluorescent markers illuminate small areas of actual localization while preserving most of the healthy tissue.

The developed technology will be optimized for use as a working laboratory technique and commercialization for use by Russian medical and biotechnological companies, in surgery, including laparoscopic, high-resolution fluorescence tomography, medical analysis, research on the effectiveness of binding of new drugs, antibodies, aptamers.

**The innovativeness of the idea**

The originality of the proposed idea lies in the use of a technique for the synthesis of gold nanoparticles (NPs) of a special shape, absorbing and emitting electromagnetic radiation at the red border of the spectral region of the visible spectrum. This area coincides with the area of ​​transparency of biological tissues. In other words, red and near infrared radiation passes through biological tissues (750-1000 nm). In the scientific group, Ph.D. Solovieva showed the ability of amino and mercapto-substituted organic compounds to stably bind to the surface of gold NPs.[[21]](#footnote-21) Under the action of light of the required wavelength, nanoparticles generate an electromagnetic field that amplifies the signal of fluorescent labels by several orders of magnitude (104-108)[[22]](#footnote-22). Strengthening the signal of label molecules in the "transparency window" of tissues (near infrared range) can be achieved through the use of particles of a certain shape - nanorods and bipyramids, whose amplification frequency shifts to this region relative to the amplification frequency of single particles.

In this project, we are going to use a synthetic approach based on a modern and simple synthesis of gold nanorods (NR), which have an adsorption peak at 658 nm, using glucose as a reducing agent. These particles are ideal amplification surfaces for the optical signal from the sulfo-cyanine-5,5-amine chromophore (Cy5,5) (and similar chromophores) because they have overlapping electronic transition wavelength regions. This chromophore was chosen because of its water solubility and the presence of amino groups in a cationic form. In our previous studies, we proved the ability of amino-substituted organic compounds to stably chemisorb on the surface of gold nanoparticles [8]. Then, after appropriate modification with functional groups, the developed plasmonic fluorescent biolabile substances in relatively low concentrations can allow analysis and surgical manipulations with the naked eye, as well as create high-resolution images of biological tissues. This approach has no close analogues and will be applied for the first time for the purposes of medicine and biotechnology.

**Product description**

**Fluorescent labels**

The product is in liquid form, storage in vials, test tubes, disposable injection ampoules at a temperature of 4˚ s up to 6 months (depending on the results of product stability tests). It is a concentrated aqueous suspension of colloidal marker particles. Biologically harmless (after confirmation of the results of relevant tests). Depending on the intended purpose, it can have a different form of release: for mapping internal organs - disposable ampoules for intravenous administration, for ex vivo and in vitro analysis - vials and test tubes. In all cases, marking in accordance with GOST R ISO 152231-2014 "MEDICAL PRODUCTS Symbols used in marking on medical devices, labels and accompanying documentation."

The scientific and technical result of this project is the development of a technology for the synthesis of nanocomposite labels for fluorescence tomography, whose accuracy (detection limit of analyzed molecules / biomarkers) will exceed existing solutions for medical imaging / analysis of the content of an object in an analyte of biological origin by more than an order of magnitude.

**Equipment requirements**

Imaging / analysis equipment similar to that used for conventional molecular fluorescence imaging / optical studies does not require structural modifications or additional software development.

The product has two forms, adapted to work with 633 and 785 nm excitation lines - red and near infrared light. The former can be used to work without additional equipment, since the emitted light is on the border of the visible area. The second modification is intended for a more subtle sensitive diagnosis of areas located deep in the patient's tissues, since the secondary radiation has less scattering by biological tissues. Both lasers are already used in molecular diagnostics and tomography with conventional fluorescent labels.

**Description of consumers**

According to the International Agency for Research on Cancer, 314 thousand cancer patients died in Russia in 2018.

In total, 543 thousand cases of diseases were registered.

From the point of view of a business strategy, our company is focused on several consumer groups.

**Large pharmaceutical companies and private analytical laboratories**

Research laboratories of academic organizations and commercial biotechnology companies will be interested in the form of the product adapted for the respective purposes for the study of the pharmacokinetics of the active pharmaceutical substances being developed.

Large pharmaceutical companies, such as Geropharm and BIOCAD, combine world-class research centers, modern pharmaceutical and biotechnological production, preclinical and clinical trials that meet international standards, and also invest in technological development and the creation of modern pharmaceutical infrastructure.

Currently, private analytical laboratories such as Helix are popular due to distrust of free medicine and the difficulties of registration;[[23]](#footnote-23)

**International trading platforms**

After successful tests on cell cultures and biological matrices, the product can be commercialized for ex vivo and in vitro analysis. Ex vivo - express analysis of cells of a living patient without introducing markers into the body by biopsy - removing tissue samples and working with them. In vitro - laboratory analysis, the most common analytical one, involves sample preparation. The consumer in this segment can be the domestic company OPTEK LLC, which is represented in the analytical equipment segment and has independent developments in the field of design solutions for equipment for Raman spectroscopy. Also promising is cooperation with international companies Sigma-Aldrich Merck, Lumiprobe. The sale will be carried out through the sites of companies that have a name in the market of equipment and new technologies and materials, i.e. according to the B2B model. Thus, we will be able to provide scientists and specialists with our innovative product.[[24]](#footnote-24)

**Private (B2B market) and public clinics (B2G market)**

Of course, one of the most important consumer segments that we focus on are doctors and clinics, both public and private. It is known that today there is already medical equipment that will allow a doctor to work with our tags. The advantage will be that the accuracy of our marks exceeds existing visualization methods. Thus, doctors, including surgeons, will have a great advantage in diagnosing and removing cancerous tumors, which will increase patient survival, shorten the time of postoperative treatment and improve their quality of life.

The developed technology will be optimized for use as a working laboratory technique for use by Russian medical institutions and biotechnology companies. Since there are no analogues of the development, it is planned to successfully enter the international market.

Areas and practices in which the labels will be used include: rapid ex vivo biopsy and in vivo imaging (in intensive care units, operating rooms, intensive care units), 3D mapping of problem organs, in vitro laboratory clinical analysis of samples. The technique promises to give good results for early tumor diagnosis due to its high sensitivity at low concentrations of biomarkers, i.e. for small tumors that are difficult to localize with conventional methods.

**Scientific and practical groundwork**

Labels based on the use of a fluorophore modified by a specific antibody (molecules that emit light in advance of a given frequency, attached to a protein capable of adhering to antigens - certain biomarkers of the surface of cells of interest, for example, cancerous ones) have begun to be used in medical practice in the last decade and have already proven their worth efficiency.[[25]](#footnote-25)

In parallel, in the field of nanomaterials science, over the past 20 years, many techniques have been developed that make it possible to synthesize plasmonic nanoparticles that amplify the optical signal by several orders of magnitude (some articles deal with the determination of single molecules).[[26]](#footnote-26)

Over the past three years, our research group has shown the ability of optically active molecules to form stable structures with such nanoparticles with an optical response enhanced up to 105 times[[27]](#footnote-27). The range of optical activity of the proposed labels lies in the region of transparency of biological tissues, making it possible to visualize objects without interference deep in the tissue, or conduct laboratory analysis with the maximum degree of selectivity in the absence of a signal from other biological objects due to the directed synthesis of plasmonic nanoparticles with optical activity in the corresponding area.

While the efforts of scientific groups of academic and commercial structures around the world are aimed at the development of drugs for cancer of various principles of action, only a few publications on the use of plasmon labels for the determination of cancer biomarkers can exist in the literature of recent years, and all of them describe only potential use for laboratory analysis in situ. The logical idea is to combine these new technologies to develop new generation fluorescence tomography labels. Grant of the Russian Science Foundation No. 17-73-10209 "Obtaining and research of the optical properties of new organometallic substrates with zones of" hot spots "promising for use in highly efficient components of nanophotonics" 2017-2019 (completed)

SRS by Odintsova OV, 2019, SRS theme "Adsorption and optical response of sulfur-containing stilbene derivatives in noble metal sols"

SRS Smirnova AN, 2019, SRS theme "SERS spectroscopy and quantum-chemical modeling of conjugated aromatic amines under conditions of adsorption on silver nanoparticles".

**Practical groundwork**

Equipment of SPbSU laboratories, access to the resource centers "Nanotechnology", "Geomodel" and "Laser" of the SPbSU Science Park, contacts with PSPbMU named after Pavlova, BIOCAD, OPTEC, FSBI NMITs im. V. A. Almazov"

**Intellectual property planned to be created**

* Patent for the technology of synthesis of plasmonic tags for biotechnological analysis and medical diagnostics
* The data that will be obtained during research on biological objects and the possible technological solutions applied based on their results will be new;
* The method of working with plasmonic tags and signal registration may also be different and subject to legal protection.

# 4.3 Marketing plan

Our goal is to attract as many medical laboratories and hospitals as possible. The company operates in the B2B field, so personal sales and placement in thematic magazines will be the main means of promotion. Moreover, a website will be created and SEO-promotion will be launched. Creation of a website with promotion will cost 70,000 rubles, entertainment expenses with printing will cost 30,000 per year.

**Determination of the mission of the enterprise**

The mission of the enterprise is to be able to find a patient's cancerous tumor and remove it while preserving the patient's living tissues. This opportunity will raise medicine to a new level.

At the moment, this option does not seem to be possible, since when removing cancerous tumors, the doctor also touches living tissues. In our system, the doctor does not touch living tissues, since the tumor is highlighted.

**SWOT-analysis**

|  |  |
| --- | --- |
| **Strengths** | **Weaknesses** |
| New technology  Safety proven by preclinical tests  Ease of use  Availability | Long-term certification  Large capital required to obtain patent and certification |
| **Opportunities** | **Threats** |
| Entering the international market due to the low cost of technology  Developing tumor treatments beyond diagnosis | Possible distrust of development  The threat of the emergence of competitors  The threat of clinical trial failure |

*Table 4. SWOT-analysis*

3) Determination of the goals and strategy of the organization as a whole

Target: at least 15 partnerships with different healthcare providers in 2022

Strategies: Leverage direct sales through personal contacts.

To do this, you need to attend events in the field of medicine and biotech, communicate with representatives of private and public medical institutions.

4) Conducting a survey among decision-makers

In order to better understand my clients, I conducted in-depth interviews with representatives of private clinics. The aim of the survey was to understand whether they are ready to buy our product, at what price and what documents they need. One of the objectives of the interview was customer segmentation.

Here is a list of questions that were asked to company representatives:

1. Tell us about your company: main areas of activity?
2. How many people do you have?
3. How do you diagnose cancerous tumors now?
4. What solutions do you use?
5. How satisfied are you with them?
6. What would you like to improve?
7. What are the characteristics of your choice of supplier?
8. Which supplier will you definitely not work with?

The sample consisted of 7 representatives of cancer centers, private and public clinics, as well as purchasing departments of Biocad and Novartis

Key insights from the interview:

1. The audience can be segmented into 4 groups according to the degree of attractiveness:

* multidisciplinary private clinics, whose values ​​are in an innovative approach
* specialized cancer centers that use their own methods of tumor location, but are interested in a more professional approach
* government clinics that choose cheaper providers
* R&D departments of companies that study cancer

1. During the interview, we found out that now it takes about 700 rubles on average to diagnose cancer in one patient, it depends on the area being examined. Our substance allows you to diagnose cancer for 300 rubles.
2. Now the main diagnostic methods in clinics are fibrogastroduodenoscopy, video colonoscopy, colposcopy and ultrasound. However, all these diagnostic methods cannot accurately determine the location of the tumor and healthy tissues are still damaged before the operation.
3. In order to buy from us, it is necessary to supply the substance on time, train doctors and provide information support. A prerequisite is the availability of all the necessary certifications. All this is taken into account in our business plan.

# 4.4 Organizational plan

**Organizational and legal form**

Our company is a limited liability company. The choice of this organizational and legal form is determined by the existence of the possibility to contribute different shares to the authorized capital, but at the same time ensuring all participants with equal rights. Moreover, with this organizational and legal form, it is easier to interact with the university, which, according to our calculations, will have a 33.3% share in the enterprise.

**Control scheme**

In our project, the following management scheme is assumed: the general management of the enterprise is carried out by the general director, who is subordinate to the technical and commercial director. The commercial director is responsible for sales, product and customer service management. There are two synthetic engineers reporting to the technical director. The duties of the CEO include conducting operational activities, developing the enterprise, monitoring compliance with enterprise standards, working with personnel and interacting with partners. The accounting department of the company will operate on an outsourced basis, the cost is 3,000 rubles per month.

**Wage**

Below are the work schedules and salaries of employees.

|  |  |  |
| --- | --- | --- |
| **Position** | **Amount** | **Salary (rub)** |
| CEO | 1 | 30 000 |
| Commercial Director | 1 | 25 000 |
| Technical Director | 1 | 25 000 |
| Synthetic engineer | 2 | 18 000 |

In total, the monthly amount of expenses for the payment of salaries to employees will be 116,000 rubles

# Project team

|  |  |  |  |
| --- | --- | --- | --- |
| **Full name** | **Role in the project, position** | **Responsibilities in the project** | **Education and regalia** |
| **According to the competitive application** | | | |
| Smirnov Alexey Nikolaevich | Chemist, team captain | Project planning, technology development | BSc 01.03.04 "Chemistry" 2019 SPbU, 1st year master student |
| Odintsova Olga Vladimirovna | Chemist | Chemical synthesis, optical research | BSc 01.03.04 "Chemistry" 2019 SPbU, 1st year master student |
| Lashkul Veronika Vladimirovna | Biologist | Particle research on biological objects | BSc 06.03.01 "Biology" 2019 SPbU, 1st year master student |
| Baranova Ekaterina Vasilievna | Manager | Economic assessment, market entry | BSc 38.03.02 "Management" of St. Petersburg State University, 2nd year master student MiM |
| Solovieva Elena Viktorovna | Scientific adviser | Scientific advice, administrative issues | PhD (Candidate of Chemical Sciences), Associate Professor of the Institute of Chemistry, St. Petersburg State University |
| **Other participants** | | | |
| Sharoyko Vladimir Vladimirovich | Biochemist | Scientific consultation, biological objects | Doctor of Biological Sciences, Leading Researcher, Laboratory of Biomedicine, Institute of Chemical Sciences, St. Petersburg State University |
| Stanislavskaya Alisa Igorevna | Chemist | Chemical synthesis, optical research | 2nd year Bachelor 03/01/04 "Chemistry" 2019 SPbSU |
| Strelnikov, Alexey Sergeevich | Chemist | Chemical synthesis, optical research | 2nd year Bachelor 03/01/04 "Chemistry" 2019 SPbSU |

# 4.5 Production plan

**Product cost**

Calculation per 100 ul - single ampoule.

To start production, a much larger amount of reagents is required (it is impossible to carry out a full synthesis cycle of 100 ul of the product)

Minimum production batch - 11 ml (100 single volumes, 1 ml for batch control)

**Taking into account the basic production chain**

|  |  |
| --- | --- |
| Raw materials | **Cost, $** |
| Fluorophores | 43,2 |
| Antibodies | 168 |
| Reagents for the synthesis of nanoparticles and surface modification | 5 |
| Total | **213,2** |

It is planned to use partner antibodies, incl. to assess the effectiveness of drugs based on them (affinity - binding).

In cooperation with pharmaceutical companies engaged in the development of antibodies (BIOCAD, Geropharm), institutes and laboratories (NMITs named after Almazov, PSPbGMU named after Pavlov)

**When switching to our own production of fluorophores**

|  |  |
| --- | --- |
| Raw materials | **Cost, $** |
| Fluorophores | 7 |
| Antibodies | 168 |
| Reagents for the synthesis of nanoparticles and surface modification | 5 |
| Total | **167** |

**A special case of application against cancerous tumors when using folic acid as a vector**

|  |  |
| --- | --- |
| Raw materials | **Cost, $** |
| Fluorophores | 7 |
| Folic acid | 2 |
| Reagents for the synthesis of nanoparticles and surface modification | 5 |
| Total | **14** |

The last approximate result requires two years of study and optimization of the production chain, subject to the success of R&D tests.

**Requirements for the production area**

During the first year, office space is unnecessary and redundant. Management and commercial personnel can work effectively remotely, if necessary, leaving for production and available sites for meetings with clients.

In the future, it is sufficient to rent a small office space to enter into trade partnerships with large commercial companies. No production facility is required during the first year. The R&D stage is cheaper to carry out using the equipment of the SPbU Resource Park and the laboratory.

In the future, a production room for a synthetic laboratory, equipped with a fume hood, will be required. Preclinical and clinical trials over the next three years are objectively cheaper to carry out under contracts with the St. Pavlova and biotechnological on their equipment using ordered samples.

Renting an office space will cost about 15,000 rubles with utilities. Payment of accounting department 2000 rubles per month.

**Production equipment requirements**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Resources** | | | | | |
| № | Name | Price | Quantity | Provider | Useful life |
| **1. Technological equipment** | | | | | |
| 1 | Pull out drobe |  |  |  | 10 years |
| 2 | Magnetic stirrer with heating | 8990 | 5 | аква-лаб.рф | 10 years |
| 3 | Laboratory glassware set | 40 000 | 1 | lenreactiv.ru | 5 years |
| 4 | Household refrigerator | 17 490 | 1 | eldorado.ru | 10 years |
| 5 | Pull out drobe | 29 970 | 3 | atmprom.ru | 10 years |
| 6 | Milli-Q Deionizer | 639 240 | 639 240 | merckmillipore.com | 10 years |
| **2. Measuring equipment** | | | | | |
| 1 | Spectrophotometer | 81690 | 1 | khimexpert.com | 10 years |
| 2 | Fluorimeter | 245 000 | 1 | khimexpert.com | 10 years |
| 3 | Room for viewing TLC chromatograms | 15 960 |  |  | 10 years |
|  |  |  |  |  |  |
| **3. Furniture** | | | | | |
| 1 | Laboratory table | 7 665 | 2 | atmprom.ru | 10 years |
| 2 | Mini bar | бесценно | 1 | eldorado.ru | 10 years |
| 3 | Chair | 3 671 | 4 | atmprom.ru | 10 years |
| **4. Technique** | | | | | |
| 1 | Office computer | 40000 | 2 | eldorado.ru | 5 years |
| 2 | IFIs | 10000 | 1 | eldorado.ru | 5 |
| 3 |  |  |  |  |  |
| **5. Protective clothing** | | | | | |
| 1 | Dressing gown KShchS, lavsan | 1 146 | 5 | komus.ru | 1 year |
| 2 | Nitrile gloves | 250 | 20 | akva-lab.rf | 1 year |
| 3 | Safety glasses | 309 | 5 | akva-lab.rf | 2 years |

**Necessary components**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| № | Name | Price | Number | Cost | TOTAL |
| Reagents | | | | |  |
| 1 | HAuCl4 · 3H2O | 11472 | 1 g | 11472 | 11472 |
| 2 | CTAB cetyltrimethylammonium bromide CAS 57-09-0 | 3000 | 100 g | 3000 | 11472 |
| 3 | Trisodium citrate dehydrate | 2000 | 100 g | 2000 | 2000 |
| 4 | Na2HPO4/NaH2PO4 |  |  |  |  |
| 5 | Polyvinylpyrrolidone 59 кДа | 3250 | 100 g | 3250 |  |
| 6 | Tetraethyl orthosilicate (TEOS) | 1000 | 10 g | 1000 | 1000 |
| 7 | (3-Aminopropyl)trimethoxysilane (ATMOS) | 7237 | 100 ML | 7237 | 7237 |
| 8 | (3-Mercaptopropyl)trimethoxysilane | 3522.86 | 25 G | 3522.86 |  |
| 9 | poly(allylamine hydrochloride) (PAH, Mw 15,000) | 4752.06 | 1 g | 4752.06 | 4752.06 |
| 10 | poly(allylamine hydrochloride) (PAH, Mw 50,000) | 2942.17 | 1 g | 2942.17 | 2942.17 |
| 11 | octadecyltrimethoxysilane (OTMS) | 4324.1 | 5 ml | 4324.1 | 4324.1 |
| 12 | BSA (bovine serum albumine) | 4500 | 1 | 4500 | 4500 |
| 13 | Glutaraldehyde | 3000 | 1 g | 3000 | 3000 |
| 14 | DSP Crosslinker | 9600 | 1 g | 9600 | 9600 |
| 15 | HS-PEG-NH2 Thiol PEG Amine 5000 kDA | 5600 | 100 mg | 5600 | 5600 |
| 16 | N-hydroxysulfosuccinimide | 4000 | 10 g | 4000 | 4000 |
| 17 | N,N'-Dicyclohexylcarbodiimide (DCC) | 3750 | 8 g | 3750 | 3750 |
| 18 | Thioglycolic acid | 1614.78 | 100 ml | 1614.78 | 1614.78 |
| 19 | Цистеин | 2700 | 50 mg | 2700 | 2700 |
| 20 | anti-FOLR1 antibody Arg25-Ser234 | 36400 | 300ug | 36400 | 36400 |
| 21 | anti-FOLR1 antibody PA5-42004 | 24347 | 100ul, 0.5 mg/mL | 24347 | 24347 |
| 22 | Cyanine7 amen | 9900 | 25 mg | 9900 | 9900 |
| 23 | Cyanine5.5 amen | 9900 | 25 mg | 9900 | 9900 |
| 24 | Cardiogreen | 9900 | 5 mg | 9900 | 9900 |
| 25 | Hydrogen peroxide 30% | 250 | 100 ml | 250 | 250 |
| 26 | Nitric acid conc | 300 | 1 l | 300 | 300 |
| 27 | Sulfuric acid conc | 194 | 1.8 kilo |  | 194 |
| Components | | | | | |
| 1 | UV lamp with filters 365 and 254 nm, 2x6 W, VL-6.LC, Vilber | 34 720‬ | 1 | 34 720‬ | 34 720‬ |
| 2 | Clamp for dialysis bag, L = 46 mm |  |  |  |  |
| 3 | Dialysis bag Zellu Trans Dialysis Tube T2, pore diameter 3.5 kDa, length 30m, width 46mm | 1 381.90 | 1 м | 1 381.90 | 1 381.90 |
| Major suppliers | | | | |  |
| 1 | www.rosmedbio.ru | | | | |
| 2 | www.sigmaaldrich.com | | | | |
| 3 | www.dia-m.ru | | | | |
| 4 | www.fishersci.com | | | | |
| 5 | lenreactiv.ru | | | | |
| 6 | broadpharm.com | | | | |
| 7 | www.abbexa.com | | | | |
| 8 | ru.lumiprobe.com | | | | |

1. Forecast of general and administrative costs associated with management for the first year

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Indicator** | **Period 0** | **Quarter 1** | **Quarter 2** | **Quarter 3** | **Quarter 4** |
| Labor costs of the management apparatus, rub. | 0 | 464 000 | 464 000 | 464 000 | 464 000 |
| Other general and administrative costs associated with business management (lease payments, payment for accounting services), rub. | 0 | 72 000 | 72 000 | 72 000 | 72 000 |
| Total general and administrative costs associated with management, RUB, (G&A Costst) | 0 | 536 000 | 536 000 | * 1. 0 | * 1. 0 |

1. Since the general and administrative costs associated with management in the second and third years will completely coincide with the corresponding periods of the first year, then we decided to present a more aggregated forecast for years.  
   Forecast of general and administrative costs associated with management

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Indicator** | **Period 0** | **1 year** | **2 year** | **3 year** |
| Labor costs of the management apparatus, rub. | 0 | 1 856 000 | 1 856 000 | 1 856 000 |
| Other general and administrative costs associated with business management (lease payments, payment for accounting services), rub. | 0 | 288 000 | 288 000 | 288 000 |
| Total general and administrative costs associated with management, RUB, (G&A Costst) | 0 | 2 144 000 | 2 144 000 | 2 144 000 |

# 4.6 Project calendar plan

## Development plan

A technology for the synthesis of nanocomposite fluorescent labels, the accuracy of which will exceed the existing solutions by more than an order of magnitude.

Science-intensive part:

1. Technique for the synthesis of plasmonic nanoparticles with desired properties;

2. Optical research;

3. Modification of plasmon particles with antibodies and fluorophores;

4. Modification of nanoparticles with aptamers conjugated to fluorophores (in collaboration with the laboratory of biochemistry of the Institute of Chemical Industry of St. Petersburg State University)

5. Biological tests;

6. Optimization of synthesis for the final product;

7. Testing (characterization) of the product.

**Commercialization:**

1. Preparation of legal (patent) protection of RIA.

2. Preparation of legal and economic basis for registration of IIP (form for in vitro and ex vivo). The creation of an SIP is possible with the support of the Endowment Fund of St.

3. Establishing preliminary plans with OPTEK LLC for commercial implementation and PSPbGMU named after Pavlova, biotech companies in clinical trials of the product form used for in vivo fluorescence imaging.

The final result is to obtain a technology for the synthesis of nanocomposite labels for fluorescence tomography, whose accuracy (detection limit of analyzed molecules / biomarkers) will exceed the existing solutions of medical imaging / analysis of the content of an object in an analyte of biological origin by more than an order of magnitude.

**Tasks to achieve the result:**

1. Development and optimization of a technique for the synthesis of plasmonic nanoparticles with optical activity at the border of the visible red - near infrared region of the spectrum (the region of transparency of biological tissues).

2. Testing the stability and ability to form dimers and agglomerates in accordance with the previously developed method for conventional plasmonic nanoparticles.

3. Modification of nanoparticles with fluorophores - Cy5.5 derivatives and analogs, optical studies.

4. Modification of plasmon antibodies, optical studies. Modification of nanoparticles with aptamers conjugated to fluorophores is an alternative approach to modification with antibodies. Aptamers are RNA oligomers with the properties of antibody proteins.

5. Tests on biomarker molecules, cell cultures, tissues, biological objects.

6. Optimization of the synthesis of nanocomposite labels in accordance with the obtained test results on biological matrices and cell cultures.

7. Product stability test: isotonic saline solution, temperature, shelf life.

8. Preparation of legal (patent) protection of RIA in accordance with international standards.

9. Preparation of a legal and economic basis for the registration of a small innovative enterprise (small innovative enterprise) in order to sell a product for in vitro and ex vivo use, negotiations with partners

10. Establishment of preliminary plans with LLC "OPTEK" in terms of commercial implementation and PSPbGMU im. Pavlova, biotechnology companies for clinical trials of the product form used for in vivo fluorescence imaging.

All stages of the development of the methodology will be carried out on laboratory equipment that is available in sufficient configuration for the project. At the moment, there are reagents for the first two stages of chemical synthesis, optimization and optical studies are underway. For optical research, there is access to the equipment of the resource centers of St. Petersburg State University "Nanotechnology", "Geomodel" and "Laser".

Funding research trips under G-Risc research exchange agreements to conduct research on biological matrices and cell cultures on the equipment of the Free University of Berlin, as well as the STEPS program of the University of Tokyo on mice. The details of cooperation are academic in nature, have already been agreed and will not affect the interests of the applicant of this project at the stage of commercial implementation. Cooperation with the St. Petersburg State Medical University named after V.I. Pavlova.

## Commercialization plan

**I. First stage**. Implementation of the release form for research and medical tasks that do not require clinical trials for ex vivo administration and in vitro studies.

After successful tests on cell cultures, biological matrices and in academic collaboration with the Laboratory of Biochemistry, St. Petersburg State University. The creation of a MIP is planned. There is a possibility of creating an SIP with the support of St. Petersburg State University (Endowment Fund). At this stage, commercial implementation of the product for ex vivo and in vitro analysis is possible. Ex vivo - express analysis of cells of a living patient without introducing markers into the body by biopsy - removing tissue samples and working with them. In vitro - laboratory analysis, the most common analytical one, involves sample preparation. At the moment, negotiations are underway with representatives of the domestic company OPTEK LLC, represented in the analytical equipment segment, which has independent developments in the field of design solutions for equipment for Raman spectroscopy. The sale will be carried out through the sites of companies that have a name in the medical analytics market, i.e. according to the B2B model. Start of a marketing company.

At the moment, we are in correspondence with the following sites:

* primebiomed.ru
* particle-works.com
* ruixibiotech.com
* aurion.nl
* nanocomposix.com
* appliednanoparticles.eu
* americanelements.com
* sigmaaldrich.com
* lumiprobe.com

**II. Second phase.** Implementation of an injectable release form designed for in vivo administration.

At the first stage, the project will start receiving funds from implementation to support production, research and further development. After successful testing of laboratory animals, it is planned to proceed to the second stage.

As with any objects (labels, drugs) intended for in vivo administration, clinical trials are required. Clinical trials, as a rule, consist of three stages in accordance with the legislation and take time, therefore preliminary contacts and agreements will be established at the first stage. In addition, research and production facilities must be equipped and certified for good laboratory and manufacturing practices. It is planned to work with the St. Petersburg State Medical University named after V.I. Pavlova under possible research contracts with analytical and biotechnological companies, for clinical trials, as well as for possible production by partner companies until their own certified production site appears.

At the first stage, the purchase of fluorophores for the modification of nanoparticles with a resonant optical region will be carried out according to the commercial proposals of existing manufacturers. However, the working concentration of the obtained labels will be orders of magnitude lower than the working concentration of molecular fluorophores, thus, the slightly higher real cost of “one” label will be leveled.

In the case of successful trials of the use of labels for hyperthermia therapy, the product will not have competitive players in the field of theranostics (a modern trend that combines therapy and diagnostics), the cost of the product will be determined by the elasticity of demand in the monopoly market.

## Calendar plan

**First year**

The first stage will be devoted mainly to the synthesis of nanocomposite fluorescent labels based on nanoparticles of noble metals and fluorescent organic compounds.

1. First-second month: Synthesis of bipyramidal and rod-shaped nanoparticles with optical mode at the red border of the visible region - near infrared.[[28]](#footnote-28)[[29]](#footnote-29)
2. June 2020: A month trip to the G-Risc research exchange agreement to conduct research on biological matrices and cell cultures on the equipment of the Free University of Berlin using a confocal Raman pump-probe microscope. Study of the passage of anti-FOLR1 and folic acid conjugated labels across the cell membrane.
3. The third-fourth month: Optimization of the synthesis method, stability testing, study of dimer formation according to the previously developed method. [[30]](#footnote-30)Dimers of nanoparticles allow achieving greater signal amplification due to the effect of overlapping two electromagnetic fields generated by the particles. Optical research.
4. Fifth-sixth month: Modification of nanoparticles with fluorophores - Cy5.5 derivatives and analogs, optical studies. Modification of nanoparticles with aptamers conjugated to fluorophores is an alternative approach to modification with antibodies. Coating of nanoparticles with silicon oxide followed by addition of sulfo-Cy5.5 to hydroxyls of the silicon surface in an aqueous medium at sulfonyl groups (esterification).
5. Sixth to eighth month: Modification of particles with antibodies, optical studies.
6. Ninth-twelfth months: optimization of the synthesis of nanocomposite labels in accordance with the results of tests on biological matrices and cell cultures, seeking additional funding, drawing up reports.
7. Seventh-twelfth month: preparation of a legal and economic basis for registration of a SIE with the aim of selling a product for in vitro and ex vivo use, negotiations with partners.

According to the results of the first year, all synthetic stages of the development of the synthesis of nanocomposite labels will be carried out.

**Second year**

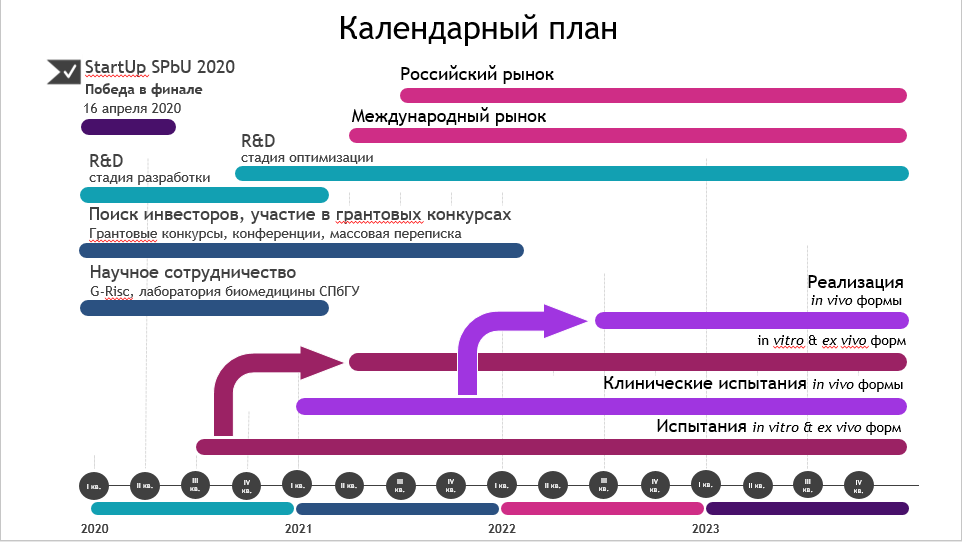
The second stage will focus on optimization of synthesis methods, research in biological objects and the establishment of partnerships and commercial agreements. Discussion of preliminary plans with OPTEK LLC in terms of commercial implementation and PSPbGMU im. Pavlova, biotechnology companies in terms of clinical trials (not limited by the time interval).

1. First-second month: optimization of the synthesis of nanocomposite labels in accordance with the results of tests on biological matrices and cell cultures.
2. The beginning of the implementation of forms for in vitro and ex vivo studies. Most of the domestic suppliers are distributors of foreign companies. Effectively interest, first of all, large foreign trading platforms.
3. The first to the ninth month: Own research on biological objects in cooperation with the interdepartmental laboratory of biochemistry, St. Petersburg State University, DKI (preclinical tests)
4. Investigation of the influence of differences in the stress factor of cell metabolism from CTAB-stabilized nanoparticles and coated with silica on cell cultures. Optical tests.
5. Third to fifth month: Stability test: isotonic saline, temperature, shelf life.
6. Fifth-twelfth month: transition to testing on laboratory animals, analysis of results, CI (clinical trials)
7. Fifth-seventh month: preparation of legal (patent) protection of RIA in accordance with international standards.

**Third year**

1. Expansion of the product line
2. Organization of your own synthesis of phosphors
3. Implementation of the in vivo diagnostic form
4. Market expansion
5. Implementation through State purchases

**Plan-diagram**



# 4.7 Financing plan

Taking into account the projected demand and the planned market coverage, a financial plan was prepared, where with the required investment of 3,214,224 rubles, the projected NPV is 24,349,598 with a payback period of approximately 1 year.

The product margin is 50%. The internal rate of return is 57%, which makes the project attractive to investors. Below are the quarterly calculations to determine the internal rate of return and the project's net present value.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Product | It is planned to produce, pcs. | | | | | Price rub. | Total year 1 | 2 Year | 3 Year |
| Period 0 | Quarter 1 | Quarter 2 | Quarter 3 | Quarter 4 |
| Drug | 0 | 1358 | 1358 | 1358 | 1358 | 2108 | 5 430 | 54 300 | 81 81 450 |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Operating cash flow planning | | | | | | | | |  |
| Indicator | Expense type | Period 0 | Quarter 1 | Quarter 2 | Quarter 3 | Quarter 4 | Total year 2020 | Year 2021 | Year 2022 |
| Revenue, rub. (Revt) |  | 0 | 2 861 542 | 2 861 542 | 2 861 542 | 2 861 542 | 11 446 169 | 114 461 685 | 171 692 528 |
| Operating costs for production, rub. (ProdCostst) | VC | 0 | 2 443 695 | 2 443 695 | 2 443 695 | 2 443 695 | 9 774 779 | 78 451 790 | 116 605 685 |
| Commercial and administrative costs, RUB (SG & ACostst) | FC | 0 | 536 000 | 536 000 | 536 000 | 536 000 | 2 144 000 | 2 144 000 | 2 144 000 |
| Direct sales and marketing costs, RUB (S & MCostst) | FC | 0 | 100 000 | 100 000 | 100 000 | 100 000 | 400 000 | 400 000 | 400 000 |
| Operating costs, rub. (OpCostst) |  | 0 | 2 543 695 | 2 543 695 | 2 543 695 | 2 543 695 | 10 174 779 | 78 851 790 | 117 005 685 |
| Depreciation deductions, rubles (Dept) | FC | 0 | 38 482 | 38 482 | 38 482 | 38 482 | 153 928 | 153 928 | 153 928 |
| Profit before tax and interest payments, rubles (EBITt) |  | 0 | 279 365 | 279 365 | 279 365 | 279 365 | 1 117 462 | 35 455 967 | 54 532 915 |
| Current income tax (Taxt) | VC | 0 | 19 556 | 19 556 | 19 556 | 19 556 | 78 222 | 2 481 918 | 3 817 304 |
| Operating Cash Flow (OCFt) |  | 0 | 259 810 | 259 810 | 259 810 | 259 810 | 1 039 239 | 32 974 049 | 50 715 611 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Investment cash flow planning | | | | |
|  | Period 0 | Year 1 | Year 2 | Year 3 |
| Investment costs, rub. (InCostst) | 3 214 224 | - | - | - |
| Non-current assets at residual value, rubles (FAt) | 1 306 529 | 4 841 296 | 4 225 585 | 3 609 873 |
| Net working capital, RUB (NWCt) | - | - | - | - |
| Invested capital, rub. (ICt) | 1 306 529 | 4 841 296 | 4 225 585 | 3 609 873 |
| Depreciation deductions, rubles (Dept) | 1 306 529 | -         153 928 | -            153 928 | -          153 928 |
| Investment cash flow, RUB (ICFt) | - | 153 928 | 153 928 | 153 928 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Free cash flow planning | | | | |
|  | - | 1 039 239 | 32 974 049 | 50 715 611 |
| Operating Cash Flow (OCFt) | 3 214 224 | -                    0 | -                       0 | - |
| Investment cash flow, RUB (ICFt) | -              3 214 224 | 1 039 239 | 32 974 049 | 50 715 611 |
| Free cash flow (financial cash flow), rub. (FCFt) | - | 1 039 239 | 32 974 049 | 50 715 611 |

|  |  |
| --- | --- |
| WACC\_ annual = discount rate | 0,14 |
| DPP | 1 year |
| NPV | 24 349 598 |
| IRR | 54,18% |

# 4.8 Project performance assessment and risk analysis

High probability of receiving government support. Our project complies with the parameters of the Healthnet-NTI roadmap, namely the sections:

• "Preventive medicine": to prevent the development of diseases, taking into account an individual approach to diagnosis, treatment and rehabilitation;

• "Biomedicine": Segment of the market for personalized medicine, new medical materials, bioprostheses ...

**And is aimed at achieving the expected results:**

• 2035: 70% of Healthnet products have a full cycle in the Russian Federation;

• Leadership in global markets;

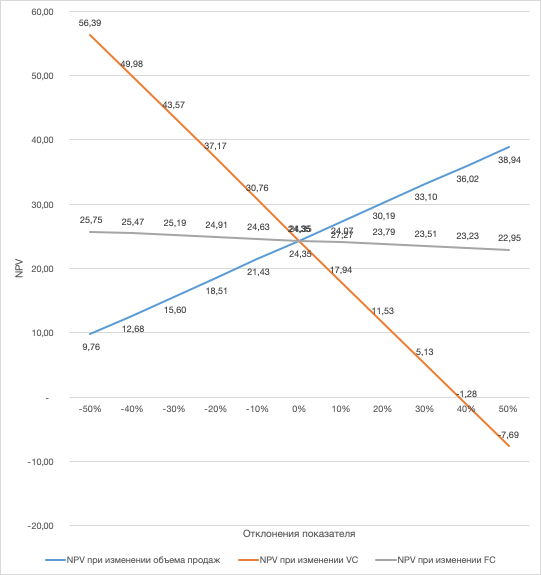
• Growth in the number of Russian technology companies, issued international patents, the volume and share of revenue in the domestic and international markets;

• development ... for laboratory diagnostics and scientific research;

• A shift towards preventive medicine;

• Conducted research work on the development of new technologies ... including the use of biophotonics approaches

|  |  |  |  |
| --- | --- | --- | --- |
| % deviation | NPV on sales rejection | NPV at VC deviation | NPV at deflection FC |
| -50% | 9 760 647 | 56 389 041 | 25 748 946 |
| -40% | 12 678 437 | 49 981 152 | 25 469 077 |
| -30% | 15 596 228 | 43 573 264 | 25 189 207 |
| -20% | 18 514 018 | 37 165 375 | 24 909 337 |
| -10% | 21 431 808 | 30 757 486 | 24 629 468 |
| 0% | 24 349 598 | 24 349 598 | 24 349 598 |
| 10% | 27 267 388 | 17 941 709 | 24 069 728 |
| 20% | 30 185 178 | 11 533 821 | 23 789 858 |
| 30% | 33 102 968 | 5 125 932 | 23 509 989 |
| 40% | 36 020 758 | -            1 281 957 | 23 230 119 |
| 50% | 38 938 548 | -            7 689 845 | 22 950 249 |



# Conclusion

# In this paper, a business model applicable to the biotech industry was built and tested. This business model takes into account the risks of companies associated with partners, core value and customers. Then a business plan was drawn up for the startup Light Up, including a business model.

# This model can be applied to pitch startups, where the investor can immediately see the stages of the company's development, taking into account the emerging risks, as well as the possibility of avoiding these risks. Also, the model can be used in company management, marketing, finance and operations management to understand the actions of the company.

# For further study, the following can be highlighted: consideration of the stages of value creation for biotech companies separately, emphasis on the part related to marketing and application of the model in other projects.

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