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Institute "Graduate School of Management"

**GenomeX business plan**

Master thesis

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**Business plan GenomeX**

The company's product is a spinal muscular atrophy (SMA) screening kit. Spinal muscular atrophy is one of the most common genetic disorders, occurring in an average of 6,000 to 10,000 births. About 200 children with SMA are born in Russia every year, about 16,250 people are born with SMA in the world every year.

The main distinguishing feature of our first product is its cost price, which is much cheaper than the closest analogue of SALSA MC002 SMA Newborn Screen from MRC Holland, sold at a price of 4 €, our product will be sold at a price of $ 3.5 per piece for foreign markets and 300 rubles for market of Russia. Also, our product is able to detect not only the presence of a disease, but also its carriage. While maintaining high levels of specificity and sensitivity, our product allows at least 35% to reduce the costs of private and public institutions for the purchase of diagnostic kits for SMA.

The company's strategic development plan is to launch a newborn screening pilot project in cooperation with Novartis and Roche, which are interested in funding a pilot screening program. Based on the results of the pilot screening, Novartis, Roche, Genomex LLC and a number of charitable and budgetary organizations, with the support of reputable Russian geneticists, will seek to introduce screening for SMA in Russia. Also, Genomex LLC plans to supply tests to foreign markets and is considering the possibility of opening a second laboratory abroad.

To launch this business, it is necessary to raise funds in the amount of 5,736,565 rubles. The most significant resource for running a business is medical laboratory equipment and investment in working capital. The project has a very high internal rate of return equal to 276 percent, which makes the project very attractive to the investor. This rate of return is explained by the fact that the market for screening for spinal muscular atrophy is empty and the company that enters the market first will receive most of it. Our company is the only company in Russia with such an economical screening technology for spinal muscular atrophy.

Genomex LLC is highly effective and attractive for investment, despite the risks associated with exogenous factors of screening implementation.

**Section 1. Business description and market analysis**

**1.1. Business idea**

Our know-how consists in the development of a modified oligonucleotide, which determines the main cost of the test system. Patenting our technology will provide a technological advantage in the SMA diagnosis market and will allow us to gain a foothold in it. Funds raised from the sale of diagnostic tests for SMA will be used to find and invent new genetic and molecular tests.

**1.2. Business model canvas**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Key partners**• Government• Novartis and Roche• Suppliers• Manufactures  | **Key activities**• Production of genetic tests• B2G sales of tests | **Value proposals**• Cheap and productive screening for SMA• Compatible with standard qPCR lab equipment | **Customer relations**• Achieving long-term partnerships through high quality and low costs | **Customer segments**• Neonatal centers |
| **Key resources**• Staff• Equipment• Patents• Investments | **Sales channels**• Direct sales to neonatal centers |
| **Cost structure**• Equipment purchases costs• Certification• Rent laboratory• Patenting• Salary | **Revenue streams**• Sale of diagnostic tests for neonatal screening |

**Table 1:** Business Model Canvas

**1.3. Description of the product and its value proposition**

The main product of Genomex LLC at the moment is a diagnostic kit for SMA disease. The product consists of the following components: a 96-well plate for mixing reagents and performing the test for SMA, filter paper for taking blood samples from newborns, a reagent for DNA extraction - a special CX and CE buffer for DNA extraction from dry blood stains and know-how - a reagent to determine the carriage of SMA.

This set will be supplied in bulk in branded boxes of Genomex LLC. The DNA extraction reagent and the SMA carriage reagent will be supplied in 0.3 liter plastic bottles. Each kit will include components for 96 tests. The cost of one test will be $ 1.5. Thus, the cost of one kit for 96 tests will be $ 144. Such a set will be released for 336 dollars to foreign markets and 28,800 rubles to the Russian market.

The key advantage of our product is its cost, which is a decisive factor in the market for government contracts for neonatal screening tests. Another advantage of our product is the ability to detect not only the presence of a disease, but also its carriage, which makes it possible to plan a family for parents - carriers of SMA. Also, our test is compatible with standard laboratory equipment, so it can be applied anywhere.

An additional value proposition of Genomex LLC is the possibility of delivering diagnostic kits, which opens up an opportunity for entering the world market and delivering our kit abroad. Genomex LLC is ready to build a logistics chain on its own, thereby enabling the client not to burden himself with transportation issues. Also, Genomex LLC is considering the possibility of opening additional laboratories abroad.

**1.4. Description of consumers**

The consumers of Genomex LLC are medico-genetic laboratories engaged in screening diseases of a wide profile. To this should be added the clients represented by the companies manufacturing SMA drugs, which in certain cases are ready to independently cover the costs of neonatal screening for SMA.

|  |  |  |
| --- | --- | --- |
|  | **Medical genetic Laboratories** | **Drug manufacturing Drag-manufacture companies** |
| **Purchase frequency** | Contract for a period of 1 to 5 years for the supply of tests for SMA | 1 year contract for the period of pilot screening |
| **Seeking benefits** | An economical, high-performance diagnostic test for SMA to meet the needs of the population under the state contract | Cost-effective, high-throughput diagnostic test for SMA for identifying patients with SMA |
| **Intensity of purchases** | Passive consumer | Active consumer |
| **Degree of commitment** | Low commitment | Medium commitment |
| **The degree of readiness to perceive the goods** | Moderate readiness for product perception | Moderate readiness for product perception |
| **Relation to the category** | Neutral attitude towards the category | Positive attitude towards the category |
| **Decision making method within a category** | Decision making is rational with favoritism towards domestic producers. Before buying, a large number of possible options are considered and the most suitable one is selected (price-quality-availability). | Decision making is rational. Before buying, a large number of possible options are considered and the most suitable one is selected (price-quality-availability). |

**Table 2:** Consumer’s description

**1.5. Analysis of the external environment**

According to prescient & strategic intelligence, the screening market, to which they have attributed 5 diseases, including SMA, will grow by 10.9% per year from 2020 to 2030. Also according to the publication, Fortune Business Insight is expected for the period from 2018 to 2026. the annual growth of the market for the treatment of spinal muscular atrophy by 28.9%. Such an increase in the treatment market implies an expansion of the patient base, which can be effectively achieved through the introduction of mass neonatal screening. Based on the above two figures, we assume that the growth of the SMA screening market will be approximately equal to the arithmetic mean between the two markets described above and will be about 19.9% under the baseline scenario, under the optimistic scenario, namely, with the introduction of mass neonatal screening for SMA in China, we expect the market to grow by an average of 30% per year over the next ten years. It should be noted that the growth of the market will be of an abrupt nature.

At the moment, the bulk of the market is in the United States of America, as so far only the United States has launched a nationwide screening program for spinal muscular atrophy. A number of countries are already in the process of conducting pilot screening programs. For example, a pilot program of mass screening for spinal muscular atrophy has been launched in three perinatal centers in Moscow. The same program is available in Germany, Belgium, Taiwan and a number of other countries.



**Figure 1:** Introduction of neonatal screening for spinal muscular atrophy in the USA

In order to calculate the current market size, it is worth multiplying the annual number of newborns in the United States who received an SMA screening program by the price per test.

4,000,000 (average US births) \* 0.68% (percentage of children screened) \* $ 3.5 ≈ $ 9,520,000 current market size. Add to this the number of newborns screened for SMA in pilot programs. However, their number is not known for certain, so we will not take them into account.

The recent emergence of this niche is associated with the introduction in December 2016 of the first approved drug for spinal muscular atrophy (Spinraza) from Biogen. Thus, according to the criteria of the World Health Organization, spinal muscular atrophy was included in the list of diseases recommended for mass neonatal screening, in order for the disease to be included in this list, it must meet a number of criteria that can be summarized in three points: 1.) the disease must have a high degree mortality or disability, 2.) there must be a need and appropriateness in the earliest possible diagnosis and treatment 3.) the disease must be treatable. Thus, the prerequisites for the emergence and growth of this market arose only 4 years ago, with the advent of the drug, since the third point was not satisfied earlier.

It is worth noting that in Russia the government has included the drug Nusinersen (market name - "Spinraza") for the treatment of spinal muscular atrophy (SMA) in the list of vital and essential drugs. In the future, we expect the emergence of a neonatal screening program for spinal muscular atrophy. This is evidenced by the speeches of the official representatives. “In addition to the drug supply, which we are now seeking, neonatal screening is needed, which will allow detecting gene mutations at childbirth, and we need to work with foreign drug manufacturers - if they make billions on the Russian pharmaceutical market, we can count on some concessions. It is necessary to discuss prices at the level of the executive power "- Alexander Petrov, member of the State Duma Committee on Health Protection.

Based on prescient & strategic intelligence research and our own analysis, we have concluded that an expansion of the SMA screening program can be expected over the next 3-7 years, as evidenced by the increasing number of scientific articles calling for the introduction of mass SMA screening and proving its economic feasibility. And also the number of legislative initiatives to consider the inclusion of screening for SMA in the national screening program.

Soon, we expect SMA screening to be included in the nationwide neonatal screening program in the EU, UK, Norway, Russia, Kazakhstan, Saudi Arabia, South Africa, Japan, South Korea, China, Australia, Canada, Brazil, Mexico and a number of other countries.

**1.6. PEST-analysis**

PEST analysis is a simple and convenient method for studying the macroenvironment of an organization in terms of factors that influence its functioning. Among the main factors are:

* Political;
* Economical;
* Socio-cultural;
* Technological.

As a useful tool for making long-term strategic decisions, PEST analysis is especially relevant for analyzing various sectors of the economy in which business opportunities prevail. A review of the characteristics of the external environment contributes to the development of an ideal strategy for introducing a company into the market, as well as drawing up its further action plan, taking into account possible changes in the most important areas of society. The following is a PEST analysis of the genetic testing company GenomeX, a new player in the flower market.

**Political factors**

Implementation of a mass procedure for diagnosing SMA in Russia

In Russia, it is discussing with the aim of expanding the mass neonatal screening program.

Ekaterina Kurbangaleeva, Deputy Chairperson of the Commission of the Public Chamber of the Russian Federation on Social Policy: “In Russia, the issue of a phased expansion of newborn screening was included in the list of instructions of the President to the Government of the Russian Federation within the framework of the discussion of the “National Strategy for Action in the Interests of Children” in November 2016. In addition, a set of measures is currently being implemented within the framework of the large-scale Decade of Childhood project. Changes and additions to the mass screening program for newborns and the creation of selective screening programs is not only important, but also extremely necessary from the point of view of disability prevention. Neonatal screening should be extended from 5 diseases to several dozen nosologies. First of all, we should talk about the diagnosis of diseases that have pathogenetic treatment."

Elena Belousova, Head of the Department of Psychoneurology and Epileptology, Scientific Research Clinical Institute of Pediatrics named after V.I. Academician Yu. E. Veltischeva: “The main goal of health care is to obtain an able-bodied member of society. Of course, this does not exclude the need to treat children and adults who are already disabled. But if we can prevent disability, then this will be a significant achievement."

Roche has now launched a pilot project for the mass diagnosis of SMA in three perinatal centers in Moscow. Thus, in Russia, the ground is being prepared for the introduction of a mass screening program. In Russia, about 1.4 million children are born annually, which makes it possible to predict the volume of revenue of about $ 2,800,000 at a price of $ 2 per test.

Implementation of a mass procedure for diagnosing SMA in the world

Around the world, there is an increased interest in the implementation of a mass screening procedure for SMA, which is primarily due to the fact that in recent years a number of drugs have been invented against this disease.

A pilot project was successfully completed in Taiwan to demonstrate the feasibility of introducing mass screening for SMA. In Europe, a number of countries have launched pilot projects, including a program in two Italian provinces that will screen about 65,000 newborns a year, and a program in the French-speaking region of Belgium, where three or four babies with SMA have already been identified out of about 30,000 examined. Spain to launch SMA newborn screening program in Barcelona.

**Economic forces**

Exchange rate growth

The sale of diagnostic tests for spinal muscular atrophy will also be carried out abroad, which, due to the weakening of the ruble exchange rate, will increase the company's revenue from foreign operations. However, at the stage of initial investments, the weakening of the ruble negatively affects the company due to the need to attract a larger amount in ruble terms.

Improving living standards in countries with high fertility

Rising living standards in Southeast Asia, China, Eastern Europe and a number of South American states contribute to higher budgets for social needs, including health care. Over the past century, there has been a significant drop in the level of child mortality and disability. This is due to an increase in the level of well-being and the development of medicine. There is no reason to believe that this trend should change. At the moment, the turn has come to reduce child mortality and disability by identifying and treating genetic diseases. Moreover, the development of medicine in developing countries is proceeding at a rapid pace, where the threshold of well-being crosses a certain threshold of approximately $ 8,000 per capita, opportunities arise for the introduction of mass screening programs for babies. With the development of science and economics, the number of countries introducing screening programs and the list of diseases included in mass screening programs for newborns is growing.

**Socio-cultural factors**

High level of public concern about child mortality and disability

The problems of the life and health of children are very exciting for the public consciousness, in connection with which there is always support from the community for projects aimed at helping children. There are many private charitable foundations and government organizations working on children's issues. GenomeX plans to work closely with such organizations to work with them to ensure that screening for spinal muscular atrophy is a must-have program.

Increased awareness of genetics and family planning among the population

Another global trend is the increased interest in genetics and medicine in general. Science has demonstrated its capabilities in treating and diagnosing many diseases, thereby managing to extend the average age of human life, especially in developed countries. The emergence of companies such as 23andMe, specializing in sequencing the human genome for personal needs, for example, to search for genetic diseases, restore ancestry or determine a propensity for a particular type of activity, is evidence of a growing interest in genetics on the part of society. People want to know themselves, and in order to truly do this, they need to turn to genetics.

**Technological factors**

Development of medical technologies

The development of medical laboratory equipment leads to the fact that more productive machines enter the market every year, which allows, during the decommissioning of old equipment and the purchase of new ones, to significantly increase production capacity without expanding the staff and production area.

On the other hand, technological progress leads to a decrease in the cost of genetic tests that test for many diseases at the same time. Thus, there is a risk of replacing genetic tests for one disease, including the SMA test, with a test that simultaneously screens for tens or hundreds of diseases. So far, such technologies remain too expensive.

**1.7. Analysis of the five forces of competition**

Michael Porter's analysis of the five forces of competition is used to scan a company's microenvironment. The model identifies five forces that affect competition in the industry, which allow us to assess its attractiveness:

* The threat of the arrival of new competitors;
* The threat of the appearance of substitute goods;
* Market strength of suppliers;
* Market power of buyers;
* The intensity of competition between incumbent players.

The model is based on the assumption that less influence of competitive forces on the industry implies greater opportunities for ensuring sufficient profitability of the business, and allows you to determine the relevant strategy for the organization to enter the market and develop its subsequent action plan. The following is an analysis of the five forces of competition for Genomex LLC.

**The threat of the arrival of new competitors**

The barriers to entry into the market for the production of diagnostic kits can be characterized as high. Entrepreneurs who have decided to open such a business need a high level of initial investment, first of all, for the development of their own test system or the purchase of a license for an existing one. Thus, we can conclude that the threat of new competitors coming to the market for the production of genetic sets is small and can only come from existing laboratories.

**The threat of the appearance of substitute goods**

There are many methods on the market for diagnosing SMA. However, the cost of their production exceeds ours. The main threat to our test is represented by chips that detect hundreds of diseases at once, this technology already exists. However, in the current reality, it is too expensive and impractical. Until the moment of its implementation, more than one decade will pass, if such a moment, in principle, comes.

**Market power of suppliers**

A large number of companies are engaged in the supply of material for the creation of diagnostic tests for SMA, so the suppliers' goods cannot be characterized as unique. The cost of switching to another supplier is minimal. Most laboratories have a contractual relationship with more than one supplier in case problems arise with other supply representatives. It is worth noting an important fact: the quality of the produced product significantly depends on the quality of the products supplied by the supplier, therefore the choice of the supplier of reagents plays a significant role. If the reagent is damaged in one way or another, a valid test cannot be performed. However, Genomex LLC minimizes this risk by performing incoming quality control.

**Bargaining power of buyers**

The rare genetic disease diagnostic test business has a small number of customers who shop in bulk. For a typical buyer, the product is not differentiated - it is easy for him to switch to the products of another, in fact, identical supplier. In addition, buyers are quite price sensitive, so they are constantly looking for cheaper options, as buying decisions in wholesale B2B and B2G segments are made rationally based on the price and characteristics of the product. The market power of buyers can be characterized as high.

**Intensity of competition between incumbent players**

Since the SMA screening market has just begun to emerge, there are practically no players on the market and there is no intense competition. The dominant player is the Dutch company MRC Holland.

**Section 2. Marketing and sale plan**

**2.1. Branding**

“GenomeX” - the name of our brand was not chosen by chance. First, our name plays on the English word genomics - a section of molecular genetics dedicated to the study of the genome and genes of living organisms. Secondly, this name corresponds to the chosen type of activity. Thirdly, our name refers to the X chromosome, which is common to genders and carries most of the genetic information. Fourthly, this name refers to the SpaceX company, which in 18 years of its existence was able to become a serious player in the space launch market and inspires the creators of this project.

**2.2. Product**

The company is currently focused on bringing its only product to the market, a diagnostic test for SMA. This strategy was chosen with the aim to ensure the launch of other products intended for diagnostics on the basis of this experience and partnerships.

This product was chosen as a debut product because it meets several important criteria. First, a significant increase in market volume is expected over the next few years, which will ensure the rapid pace of growth in the company's revenue. Secondly, due to the fact that this market is small and narrowly focused, there is no fierce competition among test companies. Thirdly, the problem of diagnosing and treating SMA is acutely social, which makes it possible to enlist the support of non-profit foundations for the purpose of joint actions aimed at including SMA in the list of programs that must be diagnosed.

 **2.3. Marketing strategy**

The project is building a network of organizations supporting the introduction of neonatal screening for spinal muscular atrophy. For this, the project sent letters to the Ministry of Health of St. Petersburg, twenty-eight charitable organizations and two companies producing drugs for spinal muscular atrophy.

The strategy is to launch a pilot screening in one of the cities of Russia. After that, it is planned to scale up the screening to the entire territory of Russia and further abroad.

To do this, we actively cooperate with companies producing drugs for spinal muscular atrophy. Drug manufacturing companies are willing to pay for a pilot neonatal screening program for spinal muscular atrophy in one of the cities. And then, by means of demonstrating the effectiveness of screening and treatment, the manufacturers intend to achieve the launch of a full-fledged neonatal screening program throughout Russia and in other countries.

**Section 3. Production plan**

**3.1. Technology**

The technological process of producing a test system for determining the carriage of a genetic disease Spinal muscular atrophy includes the following stages:

1. Incoming quality control of raw materials
2. Placing raw materials for storage

For storage of raw materials, a refrigerating room is used with a maintained temperature within 2-8C.

1. Dosed mixing of components in PET containers

The dosage of the components is calculated based on the volume of reagents sufficient for 96 tests with one test system to determine the homozygous deletion of exon 7 of the SMN1 gene and the carriage of one gene SMN1 with the deletion of exon 7.

1. Production control, packaging and placement of finished products in the warehouse.

When packing, the compliance of the weight of the components and the total weight of the product with the reference value is checked.

For storage of finished products, a refrigeration room is used with a maintained temperature in the range of 2-8C.

1. Output quality control.

As part of the outgoing control, the following is carried out:

- Conducting control tests of the test system using the assembled kit.

**3.2. The need for the availability of production facilities**

The room for placing the production of test systems must meet special ventilation requirements established by SNiP. The following standards are decisive for the choice of premises:

* Mandatory installation of forced-air forced ventilation.
* Air extraction from premises should be carried out both at the lower and upper levels.
* The presence of openable windows.
* The presence of an emergency ventilation system.
* The frequency of air change is 15-20 per hour.

Below is the calculation of the minimum floor space for the production of test kits.

|  |
| --- |
|   |
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|  |  |  |  |
| --- | --- | --- | --- |
|  Name  |  Qty  |  Dimensions МхМ  |  Total m2  |
|  Weighing and dosing workstation  |  2  |  2×2  |  8  |
|  Storage space for finished products  |  1  |  2×1  |  4  |
|  Storage space for raw materials and supplies  |  1  |  2×2+2×1  |  4 + 2 = 6  |
|  Passage  |  1  |  6×1  |  6  |
|  Total:  |  24  |

**Table 3:** Required laboratory size  |

JSC "GOSNIIKHIMANALIT" (St. Petersburg), Renova Lab (Moscow), Science Park of Moscow State University (Moscow), Technopark MOSMEDPARK (Moscow) and others are considered as potential landlords.

**3.3. Production capacity**

According to the calculations, the production facility and the number of workers are sufficient to produce 100 test systems per shift (8 hours), which corresponds to 2,380,800 tests / year.

This number allows you to fully cover the volume of tests for neonatal screening of all newborns in the Russian Federation, taking into account the fertility statistics expected according to the shifting generation model in 2021-2025.

**Section 4. Organizational plan**

**4.1. Organizational and legal form of the enterprise**

Medical Diagnostic Company "GenomeX" is a Limited Liability Company. It is this type of organizational and legal form that is the most optimal for our organization, since it has the following number of advantages:

* LLC can be founded with small capital;
* In LLC, the risk of each of the partners is limited to the main contribution;
* In an LLC, partners have broad management rights. All decisions on the main issues related to the management of the core business are made by the general meeting of partners, which eliminates the risk of various errors;
* LLC guarantees the continuity of the management of the enterprise;
* In an LLC, the costs of establishment and management are lower than in other companies.

**4.2. Planned personnel management scheme**

Personnel or labor resources are a set of employees of various professional and qualification groups employed at the enterprise and included in its payroll. For the medical genetic company "GenomeX" personnel are one of the most valuable resources, since the results of the company's activities, competitiveness in the diagnostic market, as well as the ability to enter new markets largely depend on the quality and efficiency of personnel. That is why a properly defined organizational structure is extremely important for the smooth and successful operation of an enterprise. The organizational structure of our company is a linear-functional structure, consisting of linear divisions that carry out the main work in the organization, and specialized service functional divisions. Linear powers are directly transferred from the boss to the subordinate, forming a hierarchy of management levels. The specific characteristics and features of the activity of a particular unit, which form the principle of functional departmentalization, correspond to the most important areas of activity of the entire company. At this stage of the company's development, the organizational structure is built in such a way as to minimize the costs of paying wages while ensuring the implementation of the main activities of the enterprise.

The Board of Founders represented by Maretina Marianna, Gusev Andrey, Baychikov Alexander and Khmelev Igor, which is the main management body of the LLC, determines the main directions of business development, approves plans and accepts reports on their implementation. The profit is subject to distribution among the founders after the obligatory payments to the budget are made. The management of the enterprise is led by the general director, who is contracted by the Board of founders.

**4.3. The need for staff**

**CEO (Alexander Baychikov)**

Responsible for

* determination of prices, conclusion of contracts, and payment of wages,
* signing documents on behalf of the company,
* assessing the success of the organization,
* managing day-to-day activities in the organization,
* preparation of budget and reports,
* identifying recruiting positions and managing the interview process,
* holding meetings with key stakeholders (customers and company members) to analyze the effectiveness of business policies, procedures and processes,
* ensuring the proper condition of the operated equipment by fulfilling the requirements for preventive maintenance and repair.

**Biologist-geneticist (technician and scientist) (Marianna Maretina)**

Responsible for

* correctness of calculations of dosages of components of test systems, development of technical specifications for production,
* development of safety procedures and other production rules to ensure protection against contamination of test systems, fire safety and proper labor protection,
* control tests of ready-made test systems,
* identifying problems that may affect test performance and fixing those problems,
* interaction with laboratory staff using test systems to obtain feedback, clarification of instructions for use, solution of emerging problems,
* implementation and compliance with quality assurance programs,
* execution of incoming quality control of raw materials,
* performing routine maintenance checks on equipment.

**Biological worker (Andrei Huseu)**

Responsible for

* implementation of the production process for the assembly of test systems,
* implementation of production control of test systems,
* compliance with safety measures.

**Chief Accountant (Igor Khmelev)**

Responsible for

* preparation of accounting reports, budgets and financial statements of the organization,
* preparation of payments,
* development and management of financial policies,
* administration of wages,
* ensuring compliance with tax laws.

|  |  |
| --- | --- |
|  **Position**  | **Requirements** |
| **Age and gender**  | **Education**  | **Knowledge, skills and abilities**  | **Minimum work experience**  | **Qualities** |
| **CEO** | 23 to 55 years old, gender does not matter | Higher professional education in the areas of "Economics", "Management", "Trade" | * The skill of managing the financial and economic activities of the enterprise;
* Skill in developing an organization's development strategy;
* Skill in planning and building business processes.
 | * Work experience in managerial positions for at least 5 years

   | * Determination;
* Responsibility;
* The ability to take risks;
* Strategic thinking;
* Striving for self-realization and success.
 |
|  **Biologist-geneticist** | 23 to 55 years old, gender does not matte | Higher professional education in the areas of "Genetics", "Biotechnology" | * Skill in working with laboratory equipment;
* Knowledge of genetics.

  | * Work experience in the laboratory at least 5 years

  |  * Independence;
* Hard work;
* Creativity;
* Responsibility.
 |

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| --- | --- | --- | --- | --- | --- |
| **Accountant**  | From 23 to 60 years old, gender does not matter | Higher professional education in the areas of "Economics", "Management" (profile "Financial Management") and additional professional training | * Knowledge of legislation in the field of taxation and accounting, knowledge of the Russian accounting system;
* Reporting skills;
* Skill of maintaining personnel records and office work;
* Knowledge of PC: MS Office, Word, Excel, "1C: Enterprise 8.2, 8.3", ZUP, Consultant +, SBIS ++.
 | Work experience as an accountant at least 3 years | * Equilibrium;
* Stress tolerance;
* Mindfulness;
* Perseverance;
* Responsibility;
* Honesty.
 |
| **Biological worker** | From 23 to 60 years old, gender does not matter | Higher professional education in the areas of "Genetics", "Biotechnology" | * Skill in working with laboratory equipment;
* Knowledge of genetics.

  | Work experience as a laboratory assistant from 1 year | * Diligence;
* Stress tolerance;
* Mindfulness;
* Responsibility;
* Honesty.
 |

**Table 4:** Team requirements

**Section 5. Calendar plan**

|  |  |
| --- | --- |
| Calendar | Plan |
| 2021 Q3 | Start of patenting and certification of the test system |
| 2021 Q4 | Preparation of the production facility in accordance with the standards of the Ministry of Health |
| 2022 Q1 | Production line launch |
| 2022 Q2 | Preparation of a new production laboratory |

**Table 5:** Calendar plam

The goal of the project for the next year is to launch the first production batch of test systems. Also, the project needs to patent the test system.

In the next 3 years, we plan to occupy more than 50 percent of the Russian market. Also, within the next 3 years, our company plans to supply more than 1,000,000 test systems to foreign markets.

**Section 6. Financial plan**

According to our preliminary agreements, the first deliveries of test systems to our customers should begin in the fourth quarter of 2021.

We plan to capture up to 36 percent market share by Q3 2024. Our confidence in obtaining such a share is based on the fact that at the moment we have no well-known competitors in Russia. First of all, this is due to the emergence of the market for screening for spinal muscular atrophy itself, so we intend to take advantage of our leadership. However, we expect that we will have strong competitors after the spinal muscular atrophy screening program is introduced in Russia.

Our model is based on an abrupt growth of the market. This is due to the fact that there are 85 subjects in Russia, which differ in terms of population. The contract is concluded between one supplier of a neonatal disease test and a constituent entity of Russia, as a rule, on an exclusive basis, that is, one supplier is selected for the entire constituent entity.

**Figure 2:** Revenue and Cost forecast for GenomeX

The calculations took into account the following assumptions:

* the work is carried out within the framework of the organizational and legal form "Limited Liability Company";
* a simplified taxation regime (STS) is used;
* for tax deductions, the method of 6% of the received proceeds is used (since the company will be registered on the territory of St. Petersburg);
* in the first periods, accounting and other third-party services are delivered through outsourcing;
* the discount rate is adopted at the level of 40%, since our project carries high risks due to its innovativeness;
* the GenomeX team plans to launch a project in Russia, but in the next six months gradually enter foreign markets, of which the US market is the most promising;

 

**Figure 3:** Revenue and income forecast for GenomeX

Also, as production expands, the financial efficiency of our enterprise will increase. This is due to the fact that the share of fixed costs will decrease relative to the proceeds received. We believe this will give us an added advantage in pricing and entering new markets. We expect to see positive cash flow within one quarter. We are negotiating preliminary sales of test kits to reach the planned targets.



**Figure 4:** Forecast of revenue, profit, number of tests produced and costs

Currently, the project is considering the following possible sources of funding:

* Venture financing through large pharmaceutical companies. The GenomeX team is in talks with Novartis, considering both options for a pilot program funded by Novartis and the involvement of Novartis as a strategic investor.
* Grants (for example, a grant from an innovation promotion fund)
* Participation in championships and start-up events (for example, participation in the Skolkovo Foundation Startup Village with a prize fund of over 24 million rubles);
* Venture financing through foundations and individual stakeholders;
* FFF and business angels;
* Own funds (investments of up to 3 million rubles are possible);
* An ICO launch is being considered in the future. The team includes a member who has experience in launching ICO for start-ups.

The active stage of the project is scheduled for the third quarter of 2021. It is from this time that the release of the first test systems will be launched. Until this time, the project is undergoing a preparatory stage, at which practical research and development is carried out at the expense of its own funds and funds received from participation in various competitions, establishing contacts with suppliers and customers.

The priority for the project is partial funding through participation in start-up competitions and (or) venture funding through various funds or individuals.

**Section 7. Risk Analysis and evaluation of project performance**

The main investment performance indicators of the project were assessed. They are shown in table. 7. The annual discount rate was taken at 40%, and the quarterly effective rate was 8.78%. The high discount rate is explained by the high risks of an innovative startup, in addition, at the moment, state regulation in the field of sales of genetic testing kits has not been determined. This creates additional risks for the implementation of the project (a complete list of risks is presented below).

|  |  |
| --- | --- |
| **NPV, thousands rub.** | **22 868 071** |
| **IRR** | **51%** |
| **PI** | **24** |
| **DPP** | **20 мес** |

**Table 5:** Key indicators of the investment attractiveness of the project

The NPV of the project is greater than 0, the PI is significantly higher than 1, and at the same time the IRR is significantly higher than the current discount rate that we have set for our project. All this testifies to the fact that the project is economically efficient and has great investment attractiveness. The risks of our project can be divided into systematic and non-systematic. Systematic risks do not lend themselves to management, while non-systematic risks can be considered and developed a strategy for their regulation.

|  |  |
| --- | --- |
| **Description of the risk** | **Mitigation** |
| Government regulation of the market for screening kits | Constant monitoring of legislation in the field of genetic technologies, hiring a lawyer, managing relations with the state |
| Supply disruptions | Careful selection of suppliers, purchase of necessary components for future use |
| Sales risks | Use of several distribution channels: domestic and foreign genetic laboratories, private and public, sales through wholesale distributors |
| Pricing risks | Due to the economy of our technology, we can set prices at a very low level, which is not available to competitors. |
| Refusal to issue a registration certificate | Preparation of documentation in consultation with professional companies. Taken into account in the initial investment in the project. |
| Refusal of neonatal screening for SMA in the Russian Federation | The possibility of entering foreign markets, the possibility of diversification of activities is being considered. |

**Table 6:** Unsystematic project risks