



**United  
Financial  
Group**

2022



## **Business plan**

### **Alginar**

Biotechnological production of a drug for the treatment of cancer

#### **1. Description of the product and the necessary funding for the sale of the drug Alginar**

Historical note: we studied more than 30,000 pages of text documents on working with melanin by the Soviet biochemist, candidate of biological sciences Svetlana Pavlovna Lyakh, who devoted more than 30 years of her scientific career to studying and working with the black Antarctic yeast "Nadsoniella nigra var. Hesuelica. The drug has been named "AstroMelanin". Subsequently, Svetlana Lyakh received confirmation of the very high antioxidant activity and anticancer properties of this drug. In addition, as a result of research, a positive effect was obtained on a number of other diseases, such as type II diabetes mellitus, gastric ulcer, and bronchial asthma. The development received positive feedback and support from the heads of three leading oncological centers in Russia, who assessed the drug as promising and reflecting the latest methods in cancer treatment. Biotechnological production of a drug for the treatment of cancer Production of a safe preparation from the strain of black Antarctic yeast Nadsoniella nigra var. Hesuelica" for the treatment of various types of cancer.

A drug for immunoprophylaxis and immunocorrection of the antitumor immunity system, an immunomodulatory drug with a wide spectrum of action.

Non-specific non-toxic or weakly toxic antitumor immunomodulators, necessary to increase the antitumor resistance of the body, are increasingly used in complex treatment and for the prevention of malignant neoplasms, which is justified, firstly, by the fact that the progression of a tumor disease is usually accompanied by the development of an immunodeficiency state and, secondly, by the fact that the presence of specific antigens associated with tumors of various genesis was found on the surface of cancer cells, which, however, do not always cause a tense immune response.

For 2 years of work, we have completely restored the laboratory technology for the production of melanin from the strain of black Antarctic yeast *Nadsoniella nigra* var. *Hesuelica*.

## **2. Trouble in the world**

According to WHO estimates, cancer is the leading cause of death in the world. According to GLOBOCAN, in 2020, there were 19.3 million new cases of cancer registered worldwide and more than 11 million people died.

The annual increase is between 3 and 5%, and by 2040 it is expected, to grow to 28.4 million new cases per year. In Russia, more than 600 thousand people fall ill with cancer every year.

## **3. Economic overview**

The cost of treatment for the annual course of treatment:

Avastin is \$13,000

Gerceptin is \$17,000

Keytruda is \$150,000

Kimriah's drug is \$450,000

This is without taking into account maintenance therapy and other procedures to restore the body.

However, these drugs do not give guarantees for a complete cure, and new site of the disease may appear after a while. In addition, all these drugs have a large number of side effects on the body.

According to the US National Library of Medicine National Institutes of Health 2017:

- average cost of developing one drug in 2017 amounted to \$793 million
- average development time for one drug is 7.3 years
- average profit from the sale of one drug per year \$330 million

Expenditure on medicines used to treat cancer patients has more than tripled in 10 years:

- 2011 total spending \$56 billion
- 2021 total spending \$187 billion

Expected, that over the next 5 years, the market's growth will reach \$280-\$300 billion.

Sales volumes of drugs for the treatment of cancer, according to S&P Global Market Intelligence for 2020:

Keytruda - \$14.38 billion

Eliquis - \$14.12 billion

Revlimid - \$12.1 billion

Eylea - \$10.7 billion

Imbruvica - \$9.4 billion

#### **4. Potential buyer**

At the initial stage of sale, the drug will be registered as a dietary supplement, and it will be sold through pharmacy chains and online platforms.

We already have an interested partner (a Russian manufacturing company with extensive experience in the production, sale and promotion of dietary supplements), ready to promote and sell our drug.

The next stage is preclinical and clinical studies, as a result of which the drug will become of interest to medical institutions and clinics involved in the treatment of oncology, as well as individuals who need effective and safe treatment.

There is already a demand for the drug at this stage, since it has a rather long history and positive results of use.

## **5. Why people will buy from us**

Our drug is non-toxic and completely safe for the body, unlike other oncological drugs used. Our drug is recommended for both treatment and prevention, due to the absence of any harmful side effects on the body.

We are the exclusive and sole manufacturer of this drug, with full rights to the full production technology.

### **Stage 1. Launch of small production.**

#### **Target:**

- Start production and work out the technology for the industrial production of the drug
- Register the drug as a dietary supplement
- Start selling dietary supplements
- Collect statistics and reviews on the use of the drug
- Issue patents for the development of the drug
- Create market demand

#### **Production:**

Planned production capacity: 1 kg of melanin per month

1 kg of melanin = 500 monthly courses of the drug

**Expenses for the first year:**

Equipment: \$ 757,000

Payroll fund: \$ 143,000

Purchase of raw materials for production: \$ 127,500

Purchase of reagents and consumables: \$ 7,500

Maintenance and service of equipment: \$ 4,500

Overhead expenses, household expenses: \$ 4,500

Promotion, marketing: \$ 9,000

Total summary: \$1,053,000

**Sales:**

Recommended selling price: preliminary \$225 for a monthly course

Estimated monthly revenue:  $500 \times \$225 = \$112,500$

Revenue per year:  $\$112,500 \times 12 = \$1,350,000$

**Stage 2. Organization of the full production cycle**

Target:

Start a full production cycle. Prepare for preclinical and clinical studies, collect data on the results of the use of the drug.

Production capacity: 4 kg of finished product per month

4 kg of finished products per month = 2000 monthly courses of the drug.

Profit for 1 month:  $2000 \times \$300 = \$600\,000$

Profit per year:  $\$600\,000 \times 12 = \$7\,200\,000$

**Staff:**

Director, accountant, technical director, chief engineer, supply manager, biotechnologist, equipment operator, laboratory assistant on duty, mechanic on duty, electrician on duty (repair personnel), wastewater treatment plant operator, EPR spectrum operator.

**Cost estimate for 2 years**

Purchase, installation, launch of equipment: \$4 800 000

Building construction: \$1 600 000 - \$1 900 000

Purchase of office equipment and software: \$18 000

Purchase of raw materials for production: \$200 000

Purchase of reagents and consumables: \$60 000

Maintenance and service of equipment: \$30 000

Overhead costs, wages, business expenses: \$950 000

Promotion, marketing: \$100 000

Total: \$8 058 000

Starting from the second year of operation, production is fully paid off, and we receive a net profit.

**Stage 3. Conducting preclinical and clinical studies**

The goal is to convert dietary supplement into drug.

Based on the production base and experience in the use of the drug, preclinical and clinical studies can be started. This will create an increased demand for products and recommendations from physicians for use by patients. A positive result of the research will give a huge potential for the application of products in the world market. Based on the positive results of studies, the price of the drug can be increased by 2 or more times, since the drug will receive the status of a drug with an effect confirmed by clinical studies.

Terms of testing: 3-4 years. Cost: \$2.5-\$3 million

#### **Stage 4. Scaling production**

Based on the results of preclinical and clinical studies, with a positive outcome, a decision is made to increase the production capacity.

Since the global demand for drugs for the treatment of oncology is constantly growing, and our drug is also safe for the body, has no side and harmful effects, the demand for it will far exceed the supply.

Conducting an IPO to raise additional funds in order to increase production capacity.

In the future, the sale of the company or a merger with a large pharmaceutical company is possible.

2004 - Pfizer buys cancer drug from Aventis for \$620 million

2016 - Pfizer bought out Medivation (manufacturer of cancer drugs) \$14 billion

2018 – GlaxSmithKline bought out TESARO (manufacturer of cancer drugs) \$5.1 billion

2019 - Pfizer bought out Array BioPharma (manufacturer of cancer drugs) \$11.4 billion