Project

"Oncarin – a multi bacterial drug for the treatment of cancer"

Z.M.D Group Ltd.

28 Sinai St. Netivot. **Israel** – 80200

Contact :
Dr. Mark Gaides, MD, PhD, CSO
Phone: +972 -54-6423143
E-mail: mark@zmdgroup.com

Barak Zigdon BSc, MBA – CEO
Phone: +972-54-5236882
E-mail: barak@zmdgroup.com

Funding:

For project invested about 30 years of continuous research and about 18 million US dollars of investment to study the mechanism of action of the drug and to develop therapeutic forms of the drug.

Key Executives:

1. Dr. Mark Gaides, MD, PhD – CSO
2. Barak Zigdon BSc, MBA – CEO
3. Dr. Shlomo Pundak, PhD**,** Head of Regulatory Affairs and Drug Development
4. Prof. Rina Arbesfeld Senior Lecturer, Department of Clinical Microbiology and Immunology, Sackler Faculty of Medicine- Tel Aviv
5. Ygal Dimri
   Co-Founder and Board Director Owner of a public company Y.H Dimri Construction and Development. Invested in many Startups in Israel and USA in the life science field

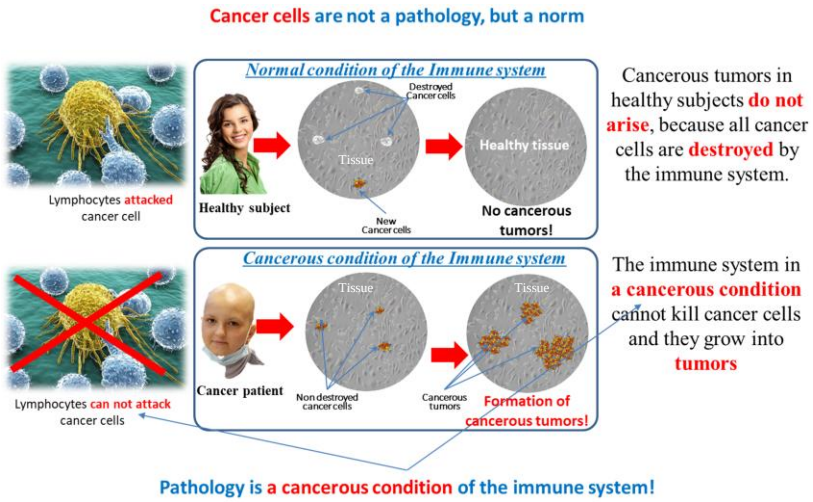
1. Z.M.D Medical Ltd develops and commercializes treatment of colon microbiome of cancer patients with bacteria of strong phenotypes taken from microbiome from special donors.
   a. The results of our studies have shown that cancer cells are formed daily in relatively large quantities (thousands or tens of thousands) in the body of any person, healthy and sick. But in healthy persons their immune system completely destroys them, and in cancer patients the immune system is weakened and cannot destroy cancer cells (cancer state of the immune system). As a result, cancer cells are reproduce and form cancer tumors, because not destroyed.
   b. The functions of the immune system completely depend on the functions of the microbiome (a set of 300 strains of certain bacteria that must be in the large intestine of a healthy person to produce the necessary set of metabolites – nutrients that provide a normal human life), because the elements of the immune system are completely dependent on the supply of metabolites, which produces microbiome.
   c. The functions of the colon microbiome are completely dependent on the state and the number of strains of bacteria that make up microbiome. Each strain of bacteria can be in two possible states:
      - in the form of a strong phenotype, which has a strong metabolism and
      - in the form of a weak phenotype with delayed metabolism.

      A healthy microbiome of the large intestine should include only the strong phenotypes of certain bacterial genotypes (strains). In patients with cancer, colon microbiome contains only weak phenotypes of certain strains of bacteria.
   d. Strong phenotypes of certain strains of bacteria of the colon microbiome can be taken from stool only from special donors, the number of which does not exceed 2% of the total human population.
   e. The drug is based on a mixture of six strains of certain bacteria with high anti-tumor activity (strong phenotypes) taken from the colon microbiome from special donors. These bacteria determine the state of all the remaining several hundred strains of other bacteria of the colon microbiome. Replacement of weak phenotypes of certain strains of bacteria of the colon microbiome in cancer patients by strong phenotypes of the same bacterial strains (transplantation of strong phenotypes in microbiome of patients) completely restores:
      - the normal state of the microbiome,
      - which completely restores the state of the immune system,
      - a normal immune system completely destroys all cancer cells and tumors (complete cure).
2. Our experiments in vitro and in vivo demonstrated the high potential of our drug for the treatment of cancer (complete cure).
3. Treatment consists in the daily intake through the mouth of capsules with a mixture of certain lyophilized bacteria of the large intestine microbiome of strong phenotypes. Usually 20-30 days of taking our medication are enough to make all cancerous tumors disappear.
4. On the basis of our bacterial preparation, yogurts can be manufactured to enhance the immune system of healthy and sick people with a weakened immune system for the prevention of infectious diseases, such as influenza and other.
5. Our solution allows us to build individual (home) and hospital diagnostic systems for early diagnosis of cancer.

Problem

Today in modern oncology, in the treatment of cancer, the main focus is on the search and artificially destroying all cancer cells and tumors with the help of surgery, chemotherapy and radiotherapy. But, probably, this is the wrong way, because despite more than a century of studying cancer, the problem of its treatment is still not solved.

The results of our studies show that in healthy patients all cancer cells are destroyed by the immune system, and in cancer patients the immune system is in cancerous condition and is unable to kill cancer cells.



As a result, cancer cells multiply and form tumors. Therefore, in the treatment first of all it is necessary to restore the immune system, and not to destroy the cancer cells, because they will be formed every day again and again. Only a restored immune system can itself destroy all cancer cells and tumors.

Solution.

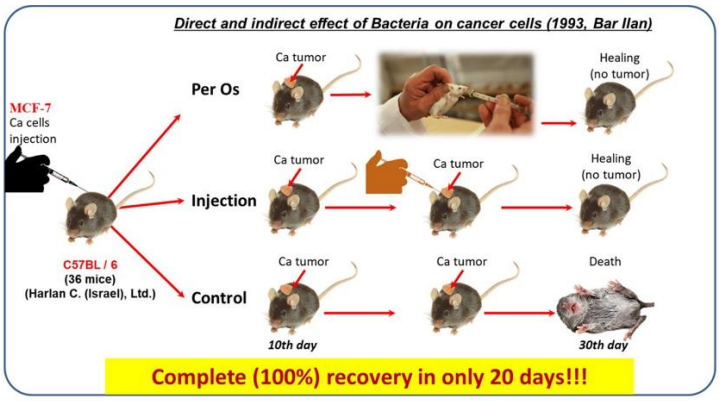
Any cells of any body systems, including elements of the immune system, require normal metabolites (amino acids, fats, carbohydrates, vitamins, etc.). If there are enough metabolites, then the body's systems, including the immune system, can function normally and the elements of the immune system destroy all cancer cells. If metabolites are not enough, then the body's systems, including the immune system, cannot function properly and their insufficiency appears. As a result, there is a cancerous state of the immune system in which she cannot eliminate cancer cells. In such cases, cancer cells are not destroyed, they multiply and form cancer tumors.

The functions of the microbiome consist in the supply to the body of all the necessary metabolites. We receive metabolites not from our gastrointestinal tract, but from the microbiota of the large intestine. We absorb food, the gastrointestinal tract mechanically (chewing food and peristalsis) and biochemically (various enzymes) prepares this food for a microbiome, which biochemically completely processes this food to the state of metabolites (amino acids, fats, carbohydrates, vitamins, etc.) that are absorbed in the blood and delivered to the recipients (cells of the body). The gastrointestinal tract uses only a few thousand of its own enzymes, because the human genome contains only a few tens of thousands of genes that can control the synthesis of several thousand enzymes. The human genome cannot be compared in its capabilities with the total genome of all strains of bacteria of the colon microbiome, because their genome is several hundred times larger than the human genome (contains several hundred thousand additional genes) and can control the synthesis of several hundred thousand additional enzymes.

Therefore, we get the metabolites we need, not from the gastrointestinal tract, but from the colon microbiome. If microbiome is normal, then all body systems, including the immune system, will receive the necessary metabolites and their functions will be normal. If the microbiome is abnormal, then the body systems, including the immune system, will not get enough metabolites and their functions will be abnormal. So appears a cancerous condition of the immune system and so appears cancerous tumors.

Conclusion: if the colon microbiome is affected (has insufficiency), it is necessary to restore it by transplanting the necessary bacteria of strong phenotypes taken from special donors. In this case, the immune system can restore its functions and itself will destroy all cancer cells and tumors. So our treatment is not aimed at cancer cells (we do not apply chemotherapy and radiotherapy and surgery), we treat only colon microbiome. It restores the immune system, and she itself destroys the cancer cells.

This was confirmed by our experiment in which the transplantation of strong phenotypes of aerobic bacteria into the intestinal microbiome of mice infected with cancer resulted in complete cure of cancer within 20 days of treatment by our drug.



COMPETITIVE CHARACTERISTICS.

Modern oncology offers the elimination of already appeared cancerous tumors and does not offer any methods of preventing the appearance of these tumors, except for the protection from carcinogens and calls for a healthy lifestyle. Naturally, this cannot give positive results, because medicine is always late (at first detects tumors and only then begin treatment). The treatment of modern oncology is very difficult, dangerous for health, roads and do not solve the problem. One can hear from oncologists that "... our patients die not from cancer, but from his treatment ...". And if the patients do not die from the treatment, they will die from cancer recurrence, because cases of complete healing from cancer are extremely rare. In other words, today in oncology there is no means for a complete cure for cancer.

And all this because modern oncology cannot say what is the cause of the appearance of cancer tumors. It is believed that in a healthy body, there are no cancer cells, and the cause of cancer tumors is the appearance of mutated cells (cancer cells) that multiply and form cancer tumors.

But this is not true. The results of our researches show that cancer cells appear in the body daily and in relatively large numbers (thousands or tens of thousands) in all, both in healthy and cancer patients. The appearance of cancer cells in the human body is a natural process that accompanies the normal processes of cell regeneration, which are destroyed in the course of normal life activity. All cancer cells must be destroyed by elements of the normal immune system (lymphocytes and other elements).

If cancer cells are absolutely in everyone, then they are not pathologies, but are the norm. What is pathology?

Pathology is the insufficiency of the immune system of the patient's body, as a result of which the newly emerging cancer cells are not destroyed daily and cancerous tumors grow from them. The appearance of the first cancerous tumors is a signal that the state of the body's immune system deteriorated to a cancerous condition.

Therefore, it is necessary to treat the immune system, and not to destroy cancer cells and tumors, because their destruction by treatment with any artificial means (surgery, chemotherapy and radiotherapy) is a Sisyphean labor, since cancer cells are formed daily and in large numbers in the body of all people, healthy and sick, regardless of treatment, and their education cannot be prevented.

Insufficiency of the antitumor activity of the immune system in the body of patients (cancer state of the immune system) is the cause of the appearance of cancer tumors. Therefore, the solution of the problem is only in the treatment of the immune system, which itself will destroy cancer cells.

Unlike modern oncology, we do not touch cancer cells, but we are working on an immune system, which by itself can destroy all cancer cells and tumors if it functions normally. In our cancer treatment technology, we focus on restoring the normal functions of the colon microbiome, on which the normal functions of the immune system depend.

Our treatment consists in replacing the weak phenotypes of certain specific bacterial strains of the colon microbiome of patients by strong phenotypes of the same strains taken from special donors. In addition to daily taking capsules with our bacteria, no other additional treatment is required.

Usually 20-30 days of such treatment is enough to completely get rid of all cancerous tumors. And there are no side effects, because the bacteria for transplantation are common bacteria that already exist in the microbiota of the colon of the patients. The difference between bacteria in the colon microbiome of patients from the donor only is that the patient has weak strains that are unable to function normally, and in a healthy donor these are strong strains that normally function.

Business Model

The drug is a capsule with a mixture of six strains of certain bacteria of the colon microbiome of strong phenotypes taken from special donors and grown in conventional biotechnology with small technological modifications in order to maintain the strength of the phenotypes. After growing the bacteria in the bioreactors, lyophilisates are prepared from them and encapsulated in dosage capsules.

It is planned to sell Oncarin in licensed pharmacies at retail. There are certain requirements for the safety of the drug (requires a small cold around 2 ° C). It is assumed that a special prescription for the purchase of Oncarin is not required, since there are no contraindications and there are no special requirements for the dosage of the drug and the conditions for its administration.

Market

Each cancer patient requires about 6 grams of lyophilized Oncarin preparation per day. The course of treatment requires about 540 grams of Onkarin (about 90 days of treatment, including the treatment itself and fixing the effect). Treatment consists in the daily taking of capsules with Oncarin through the mouth.

The manufacture cost of one gram of Onkarin is about 1 US $. The market value of one gram of Onkarin can be about 10 $ US. Consequently, the market value of Onkarin for one complete course of treatment for one patient will be about 5400 $ US.

In the world there are about 20-30 million cancer patients. And every year appears about 8-10 million new patients. This means that each year the sales of Onkarin can give about 100-130 billion US $.

Competitive environment

Today there are practically no competitors. Yes, there are many different companies that produce various probiotics. But they are not competitors for us, because donors are unknown who have taken bacteria for their preparations and unknown phenotypes of bacteria. These companies claim that their donors are practically healthy people. But today in the market there are no ways to determine the state of bacteria of the colon microbiome.

But in our company we measure the activity of bacteria. Our research shows that only specially selected people who have undergone special examinations can be bacterial donors in which only strong phenotypes of certain strains of bacteria are present in the microbiome. And among them not more than 2% of such people. All other people (the remaining 98%) cannot be bacteria donors, because in their microbiome there are only weak phenotypes of the same strains of bacteria. If we take weak phenotypes for the production of probiotics, these drugs will not have a therapeutic effect. Therefore, when buying probiotics from different companies in the pharmacy, the buyer has only 2% of the chances that he buys the active drug that he needs, and there is about 98% of the chances that the purchased drug will not have a therapeutic effect,

We have patents on ways to determine the suitability of candidates for special bacteria donors. This means that we have practically no competitors.

Patents.

Our company has:

1. 2 published patents:
   - Joint IP-Early Diagnosis of Cancer
   - Fully Owned-Bacteria Donors and Pharmaceutical Composition
2. 3 Provisionals have been submitted on May 2017.

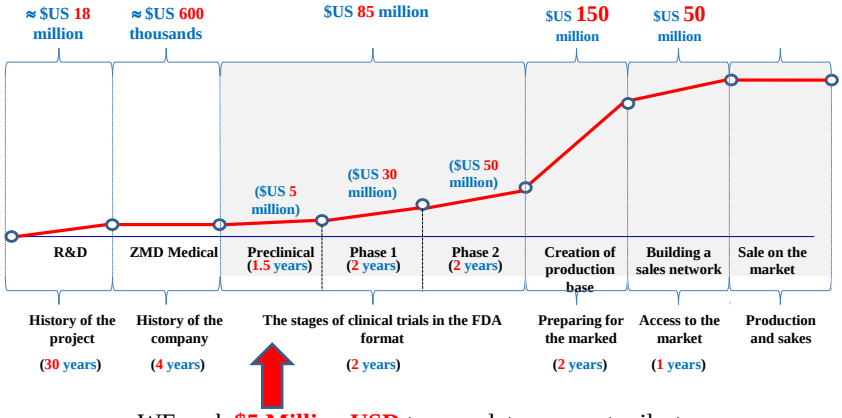
Today's state of the project.

Today, the entire technology of Oncarin production is known, the mechanisms of him therapeutic effect are known, dosages and conditions for its use are known (the protocol of application is known) and the conditions for its storage and sale are known.

For the production and sale of Onkarin, it remains to obtain permission from the Ministry of Health (FDA, CE and others) to apply Onkarin in clinical practice, to build production facilities for the manufacture of Onkarin and to arrange its sale to consumers. For this, it is necessary to go through three stages of clinical trials:

1. Preclinical stage – test of therapeutic action on animals, for example, in mice
2. Phase 1 – a test for the absence of harmful effects on the human body (test on healthy volunteers)
3. Phase 2 – a test of therapeutic effect on patients with various types of cancer

The graph below shows the time and cost of each stage.



WE seek **$5 Million USD** to complete our next milestone:
Preclinical Trials on Animals and Phase I Preparation

Today we are going the first stage (red arrow) - preclinical stage. To pass this stage we need about 5 million US dollars and about 2 years of work.

If you are interested in our offer, we are ready to answer all your questions.

Doctor Mark Gaides, MD, PhD,
CSO of ZMD Group Ltd. Company,
28 Sinai str., Nativot, Israel mark@zmdgroup.com