

# **2019 "National Science Cup" Innovation and Entrepreneurship Competition Project Business Plan**

**Team Name: UCAS-China iGEM**

**Project Name: ARK.micro**

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## **Chapter I Executive Summary**

### **1.1 Background of the project**

Our project aims to develop a biosafety medical microbial product with a high-efficiency thermo-sensitive switch as a core to build a general-purpose technology platform for microbial therapy. The use of proteases and transcription factors to build double-status switches allows the system to switch between two states under temperature activation, achieving dual functions of human body escape and off-target prevention, optimizing targeting and safety, and reducing development costs. Promote the full penetration of microbial therapies into the medical market.

### **1.2 Project planning**

We intend to improve and optimize the basic products in the initial stage, and start with the iGEM competition team and research team to develop a number of highly applicable microbial therapy systems on more mature treatment programs. In the medium and long term, we will continue to invest in independent scientific research and development, expand the types of engineering bacteria platforms; develop a variety of microbial therapy use scenarios; couple biochemical targeting to enhance the ability to prevent off-target in vivo; increase drug carrying methods to expand the application range of microbial therapy; Related industry chain.

### **1.3 Market analysis**

Microbial therapy has a strong potential for competitiveness in the medical market because it has good targeting, low cost, low toxicity, combination of drugs, repair of damaged genes or supplementation of lack of genes. As microbial therapy is still in its infancy, the amount of strong competitiveness targeting our target areas is basically blank; as our business model is oriented to independent research teams. The potential market is extensive, with a wide range of potential outcomes and strong competitiveness in multiple areas.

## 1.4 Industry competition analysis

Our main competitive quantity comes from the pharmaceutical companies that independently research and develop microbial therapies, but there are few mature commercial products at present, and the application scenarios are concentrated in the skin and intestinal environment, and the strong competitiveness of targeting our target fields is basically blank. Few companies that have proposed similar business models have entered the market and have a first-mover advantage. In addition, compared with pharmaceutical companies, we have obtained core treatment programs from scientific research teams, without investing in high-cost independent screening and research and development of specific core drugs, with controllable costs, abundant sources and lower risks.

## 1.5 Organization and personnel analysis

We build the component library and the strain library as the main production projects, build the operation team in the elite mode, and supplement the small-scale marketing team around the technical core team, gradually expand the industrial scale according to the business volume, realize the automatic production of basic components, and build mature. In vitro and animal experimental platforms.

## 1.6 Financial analysis

Our company's development is expected to go through the five-year technical platform construction period, a total of five years of mid-term market opening period and a later stable development period. The funds required in the previous period are mainly used for the construction of laboratory technology platforms and basic product research and development; the medium-term funds are mainly used for cooperation with iGEM outstanding graduate/undergraduate team and 1-2 research teams with published results. Strong microbial therapy and help them enter the market; the funds needed in the later period are mainly used to increase the visibility of the platform, hire company employees, and effectively cooperate with more researchers; and continue independent product development and product optimization. The total

investment required for the 10-year period is about 7.45 million yuan. The total profit is expected to reach 10 million yuan and the total profit and loss rate is over 30%.

## 1.7 Risk Analysis

The main risk faced by our products is that our basic products cannot be established by institutions such as FDA. The application of the standard of therapy has increased the development cycle and cost, the profit cycle has been lengthened, and the first-mover advantage has been lost. Second, the therapy developed jointly by our partners and partners has limited market recognition, limited market share and insufficient profitability. We need to strictly and fully optimize the basic products in the pre-development preparation stage, fully understand the market demand and requirements, and fully prepare for the market's first-mover advantage; set a rigorous review and screening system for the selection of cooperative projects. Consider hiring scientific consultants with practical experience to provide advice; continue to develop independent products, ensure the vitality of innovation, and gradually establish a complete industrial chain. In the case of the best development situation, you can apply for listing, or you can choose to withdraw venture capital through mergers and acquisitions.

## Chapter II Project or Company Profile

### 2.1 Project Overview

**Design high-efficiency temperature-sensitive switches for microbial therapy to discover the potential of more microbes.**

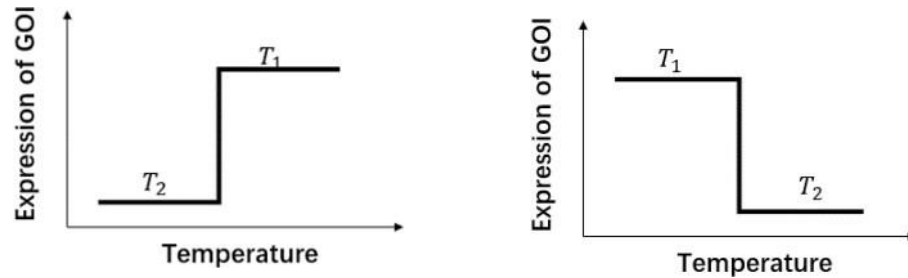
Microbial therapy has been increasingly researched in recent years, and people are beginning to pay attention to the transformation of microorganisms. At present, the treatment of diseases is still dominated by chemical drugs. High priority is given to biosafety issues, making microbial therapy unusable. At the same time, however, microbial therapy has an absolute advantage - good targeting, microbial administration, manual determination of the target to precisely control the scope of administration and intensity of administration, which is a difficult step for chemical drugs.

Our project considers biosafety issues and optimizes microbial therapy by enabling microbial human escape and off-target prevention. Provides a modular, universal, and assembleable platform for potential therapeutic applications that utilize microbes to achieve high biosafety by directly coupling the target drug or gene from the researcher to our engineered bacterial platform. Therapeutic bacteria greatly shorten the development cycle, reduce the development cost, provide opportunities for microbial therapy to enter the market and occupy the market, and greatly accelerate the development process of microbial therapy for the benefit of human health. The components we build the switch are temperature-sensitive components that are manually screened out by evolutionary means, and the temperature-sensitive switches are constructed using the temperature-sensitive components. Then use the temperature sensitive switch to carry out a series of biosafety prevention and control measures.

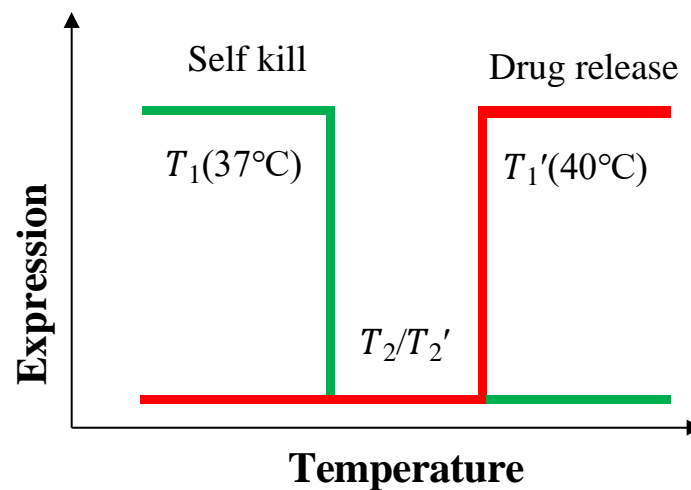
We built a bistable switch using proteases and transcription factors, allowing the system to switch between the two states with temperature activation, enabling the switch to function. At the same time we joined one

The protein degradation system can degrade the target protein expressed by the downstream gene in the on state when the switch is switched to the off state, thereby improving the response sensitivity of the entire switch.

The switching performance of the temperature sensitive switch is as follows:



The switching performance achieved by coupling two temperature-sensitive switches is as follows:



That is, we use the coupling of two temperature-sensitive switches to achieve two functions - human body escape and body off-target.

The green part is the realization of the cold-induced temperature-sensitive switch. Microbial therapy needs to introduce microorganisms into the human body, and the temperature in most parts of the human body is kept at about 37 °C. In order to prevent the engineering bacteria from being discharged by the human body, the environment is affected. The induction switch part is added to the suicide mechanism, the activation temperature is 37 °C, that is, when the microorganism is in the human body 37 °C environment, the cold induced switch is closed, the suicide mechanism is closed, when the microorganism is discharged by the human body, entering the environment, the temperature is generally lower than 37 °C, the cold-induced switch is turned on, the suicide mechanism is turned on, and the anti-escape mechanism of human microorganisms is realized. By optimizing the suicide mechanism, the escape

rate is reduced to the standard 10-10/cfu. The red part is the realization of heat-induced temperature-sensitive switch. Microbial therapy generally needs to utilize the targeting of microorganisms. The microorganisms can be modified so that microorganisms can carry or self-produce small molecules of drugs, and the targeting of microorganisms can be more quickly and accurately. The drug is released to the lesion, but if the drug has certain toxic side effects on the normal cells of the human body, then the microorganism may then damage the normal tissue cells in the human body for the microorganism that has not reached or can not reach the lesion. , causing random and strong side effects. Therefore, we consider the use of heat-induced switches, for the treatment of microorganisms that can produce drugs on their own, add genes for the production of drug molecules downstream of the heat-induced switch, and use temperature to control the production of drugs, so that manual heating can be used to treat the lesions. The temperature is raised by heating, and only when the microorganism senses above 37 ° C, or 40 ° C, the expression of the drug molecule is activated, and the microorganism releases the drug at a fixed temperature. In addition, if the biologically active off-target bacteria are freed from the human body for a long time, it may cause the body's immune response or cause other adverse effects. Therefore, the coupling of the suicide system and the anti-off target system can make the lesion not reach the lesion within a certain period of time. The engineering bacteria died. Considering the depth and location of the lesion in the human body, the therapeutic effect can be optimized by searching for the optimal in vivo survival time of the engineered bacteria. The survival time can be artificially programmed by in vitro induction of the engineering bacteria before being placed in the human body. The accuracy is optimally up to the average time standard of the division of engineering bacteria.

And this set of temperature sensitive switches has proven to be useful in a variety of microorganisms.

## 2.2 Project Service and Business Profile

1. Provides versatile microbial therapeutic engineering bacteria that have achieved anti-escape and anti-off-target functions in the body, and respond to different strains according to different therapies, such as *Escherichia coli* Nissel (probiotic strain, suitable for intestinal environment, in the intestinal environment) It is planted for about one month, and it continues to have a therapeutic effect, and the strain is discharged from the body after death, lactic acid bacteria, and inactivated *Salmonella*.

2. Provide hardware technical support, that is, fixed-point heating.

If the location of the lesion is in the human environment, such as the intestine, a bio-electronic capsule can be developed, and the electronic part senses the external signal. By tracing the electronic part, it is judged whether the capsule reaches the lesion point, and after reaching the lesion point, the remote control electronic part heats up. When the engineered bacteria in the other half of the biological part of the capsule feel the temperature change, the expression and release of the drug molecule are achieved, thereby

To the purpose of fixed-point administration.

If the location of the lesion is in the human body environment and the temperature penetration is good, the ultrasonic surface heating technology can be used to set the temperature of the body surface and the area between the body cavity and the body surface.



## 2.3 Development plan

Short-term planning:

1. In the more mature treatment programs, cooperate with relevant researchers to develop several mature microbial therapy systems and promote animal/clinical experiments;
2. Collaborate with the iGEM competition (International Genetic Engineering Competition) to assist the graduate/undergraduate team in the application of the competition results industry;
3. Recruit a young R&D team with a good experimental foundation, innovative and small-scale professional marketing team;

Medium and long term planning:

1. Expand the range of engineered bacteria platforms to provide the basis for more potential microbial therapies;
2. Develop a variety of microbial therapy use scenarios, such as cancer, inflammation, etc.
3. Develop practical microbial therapeutic engineering bacteria based on different biosafety principles;
4. Coupling biochemical targeting to improve anti-offensive ability in vivo and reduce side effects;
5. Increase drug carrying methods (such as small molecule compound outer membrane coupling) to expand microbial therapy for a wider range of chemical small molecule drugs

## Chapter III Market and Competition Analysis

### 3.1 market situation

Among the existing mainstream drug therapy markets, the earliest and most widely used are small molecule chemical drugs, but for patients, small molecule drugs often have certain biological toxicity and poor targeting, which greatly limits the disadvantages. Its scope of use, forced to extend the treatment cycle, not only increases the risk of side effects for patients, but often burdens high treatment costs. For pharmaceutical companies, the screening and development of small molecule drugs often require high human, material and financial costs, and it is far from being able to be converted into effective pharmaceutical products that enter the market among thousands of candidate molecules.

To 1%, with the development of the times, the speed of small molecule drug replacement and development optimization is far from enough to meet market demand, and the market is in urgent need of more competitive therapy.

A large part of the small molecule chemical drugs in the anti-tumor drug market act on the basic life activities of cells such as cell signaling pathways and mitotic mechanisms, and thus often have large toxicity, and the targeting is poor, so that the risk of side effects is greatly increased. In the fierce market competition, targeted low-toxic drugs such as monoclonal antibodies such as monoclonal antibodies have grown rapidly and occupy a large market share.

2017年全球肿瘤药销售额TOP10全是靶向药



Source: Research Report on Market Analysis, Forecast and Development Trend of China's Antitumor Drug Industry in 2018-2024

Precision therapy with strong targeting has strong market competitiveness and broad market prospects. Microbiological therapy based on biological autonomy has the following advantages over small molecule drugs and protein drugs:

1. Good targeting;
2. low cost;
3. Can be used in combination;
4. Gene therapy can be achieved by repairing damaged genes or

supplementing with lack of genes. However, small molecules and protein drugs can only work by reducing the activity of a certain target;

Its competitive potential is self-evident. As an emerging industry, it is of great significance to master its dominant advantages. The biggest bottleneck problem of microbial therapy is biosafety. The problem of bio-escape is a fatal hazard. Actively exploring appropriate market standards, its long-term security guarantees will help accelerate the establishment of relevant market standards, thereby rewriting the current market situation.

We strive to develop a highly biosafety standardized platform for all therapeutic microorganisms, downstream of which can be coupled with most bioavailable drugs to develop a range of highly targeted, highly sustainable, low side effects, low cost Mature microbial therapy system. At the same time, the use of engineered bacteria to target tumor lesions may re-establish a series of potential drug molecules that are limited by toxic side effects, and open up a new market.

Most of the currently known microbial therapies are still limited to the external environment. Products that are in clinical development or are already on the market are almost confined to the human environment, ie, the intestines, skin, oral cavity, etc. The products that have been marketed are used by OmniBiome for the treatment of teeth. Weekly oral microbial probiotic products, AOBiome's women's skin care products AO+ sprays, etc.; products in clinical development such as Qubiologics' ulcerative colitis therapy QBECO-SSI, AOBiome's acne therapy B-244, etc. - The engineered bacteria platform designed by us can guarantee the biosafety of the human body environment, thus greatly expanding the capability limits of microbial therapy.

As an emerging field, microbial therapy has been established in the industry for less than 10 years. It is less than 5 years since the official listing of major breakthrough therapy. The only representative enterprises in China that have the ability to develop microbial therapy are North China Pharmaceutical. - There is still a lot of new power in the field to develop competition, especially in the context of the biotechnology industry being listed as one of the country's seven strategic emerging industries. Our innovation and development are recognized by the state and What the field needs.

### 3.2 market expectation

The prospects for the development of the pharmaceutical market for our products are very broad. The demand for new and high-efficiency therapies in today's society and the concern for life and health have only increased.

For the microbial therapy market applicable to the internal environment, taking anti-tumor therapy as an example: due to factors such as life stress, environmental changes, etc., cancer is expected to surpass heart and brain disease as the global first

threat to human health, according to statistics. In 2017, the global expenditure on cancer treatment products and maintenance therapy has reached 120 billion US dollars, accounting for more than 10% of the global pharmaceutical market.

The average annual growth since 2011 is close to 9%. It is expected that the market will exceed 1470 in 2021.



**Source: Research Report on Market Analysis, Forecast and Development Trend of China's Antitumor Drug Industry in 2018-2024**

For microbial therapies for the external environment, the phenylketonuria therapy market, which is mature in scientific research and is expected to be developed preferentially, is an example: although the risk of phenylketonuria in newborns is less than one in ten thousand, Related therapeutic drugs are expensive. In 2016, the US phenylketonuria-related market revenue was nearly 4.38 million US dollars, and the market developed rapidly. The average annual growth rate in recent years reached 11%. If calculated in turn, it is expected that the market's revenue will be close to \$7.4 million in 2021 – the use of microbial therapy is expected to have the capacity to occupy more than 20% of the market.

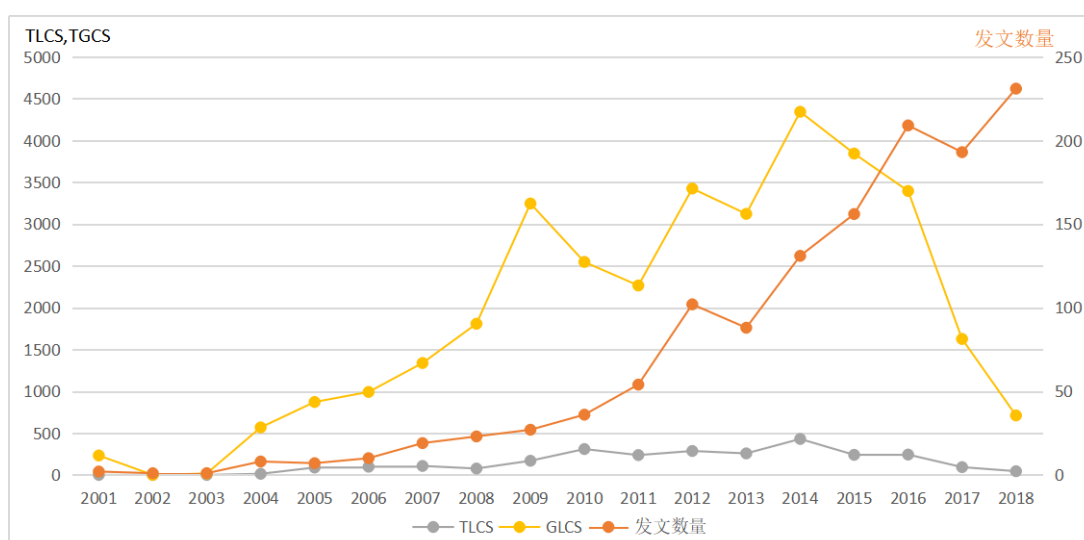
The potential market for microbial therapies is very large, although there are few microbial therapies in the market due to the fact that relevant regulations and guidelines still need to be improved and there are very few mature drugs. However, the development trend and development prospects in this field are very impressive. When the development of microbial therapy becomes the backbone of the market, our

technology platform will also usher in great development.

In addition, one of the great advantages of our products is that their development and application is not limited to the treatment of single diseases, and its application field can almost compete with traditional drugs. It has a rich source of transformable results and is conducive to sustainable development.

It is said that Qu Biologics and AOBiome are the only two biotech companies with early and late development of microbiome-targeted therapies, but these companies are hoping for the success of a drug and therefore have considerable risks. And our direct research and development of research results and application transformation can reduce the risks and costs of “wide network, low output”. Statistics on the publication of core journals related to microbial therapy in the Web of Science database, with more than 1,300 articles and the number of documents published

It has shown an upward trend year by year, and it has broken through 100 pieces/year in 2014. This year's average annual growth rate is over 10%, reflecting the booming trend in the field. In addition, both tlcs and tgcs reached the highest in 2014, namely 2014. Some groundbreaking work has emerged in the year, and most of the work after 2014 is groundbreaking.



### 3.3 Targeted market

For the commercial transformation of all potential microbial therapies, the main customers are for research teams and innovation teams engaged in the development of potential drugs for microbial therapy, which will help transform

their research results into practical applications. Relatively large pharmaceutical companies, independent research teams do not select potential drugs in large-scale, high-throughput molecular screening methods, and may lack professional team and practical experience in biosafety. The standardized microbial therapeutic engineering bacteria platform supplied by us provides technical support for accelerating the transformation of the results of independent scientific research teams, and realizes a direct leap from the in vitro experimental characterization of drug gene/drug molecules to the animal characterization of corresponding microbial therapies.

### 3.4 Marketing strategy or business model

1. Start with the iGEM competition in synthetic biology and work with a team of outstanding graduate/undergraduate students to help transform the results of the relevant projects and form an official long-term relationship with the iGEM competition. You can apply for a special award, and each year you will be given a certain entrepreneurial bonus to the winning team, and cooperate with them to transform the results and expand the popularity among the new talent groups in the field of synthetic biology;
2. Looking for research teams with published results to discuss cooperation, launching a number of highly applicable microbial therapies, promoting in vitro and animal experiments, applying for drug review to promote clinical trials, and promoting 1-2 products successfully entering the market, confirming the universality of our platform. Sex and effectiveness, open awareness;
3. Build a platform for all potential microbial therapy core drug developers, encourage sharing of potential treatment outcomes, establish a database of researchers for global researchers, regularly host collaborative exchanges, and select potential research teams to provide joint research and development funding and technical support;
4. To build a mature commercial platform and provide a transformation path for the research team. The developer only needs to provide small molecule drugs/drug genes. Our platform can build high biosafety engineering bacteria with the purpose of curative effect, which is convenient for developers to advance in vitro. Animal, clinical and other experiments;

5. Develop effective in vitro testing, animal and clinical laboratory platforms, and build a sound industrial chain.

### 3.5 competition analysis

The competition is mainly from large pharmaceutical companies that develop their own microbial therapies. Its existing marketed products and products in the late stage of clinical development have pioneered the microbial therapy market. But with the following restrictions:

1. Depending on the success of a few drugs, there is a higher risk;
2. Develop core drugs on their own, with high development costs and high product prices;

We avoid direct competition and focus on the rich scientific research results of the research team. The core is the universal platform for carrying the therapy. We do not need to invest a large amount of cost to independently screen and develop specific core drugs. The improvement of core technology focuses on further improving biosafety and expanding application scenarios. The research and development costs are much lower than those of large pharmaceutical companies.

## Chapter IV Operational Analysis

### 4.1 Production organization

Our aim is to produce a platform that can realize the body's anti-escape and anti-off target in the body, and integrate the genes provided by the collaborators. Therefore, building the component library and strain library is our main production project.

Due to limited business volume, the company focused on operation optimization and technology research and development, and did not need to build a production line. With a small number of experimental technicians as the main body of work, it is mainly divided into its own product optimization and technology research and development departments and undertaking cooperative development market application microbial therapy. department. In the middle and late stages of the company's development, 1-2 product production lines will be

built according to the business volume, and the process of gene integration and strain screening will be automated. The basic production organization will be handed over to the supervisors; a perfect in vitro testing platform and a mature The animal experiment platform realizes the efficient promotion of the follow-up therapy development, and the basic production and control are led by the technical technicians.

## 4.2 QC

1. Evaluating the biosafety of product strains by escape rate and off-target rate;
2. Assess the efficiency and fidelity of insertion of the target gene;
3. Assess the production efficiency of the target drug;
4. Assessing whether the genetic background of the product strain has a potentially harmful variation;
5. Assess the growth of the product strain, ie the growth pressure of the product strain on the applied system.

## 4.3 Organization management

It is divided into production department, marketing department, finance department and general management department.

Among them, two in the production department, one person is responsible for the management and maintenance of the production line, one person is responsible for quality control testing and screening; one person in the marketing department is responsible for maintaining the stability of the platform and communication, expanding the scope of the platform, expanding the market; one person in the finance department, responsible for financial management, accounting , the allocation of funds; the integrated management department for the core members of the company, management of the various departments to mobilize and make major decisions.If the manpower is not enough, consider taking part.



## 4.4 HR management

For the probationary staff, there is a three-month probationary period after recruiting the employees, and the employees are trained for three months, and cultivate multi-party capabilities, so that they have sufficient and appropriate understanding of the company, actively build corporate culture, and achieve teamwork; For formal employees, implement monthly performance appraisals, including attendance, work results, and colleagues' evaluations. At the same time, establish and improve the company's feedback mechanism to help improve the company's system and enhance team cohesion and cooperation.

## Chapter V Financial Analysis

### 5.1 Investment and financing analysis

Short-term financial plan (6-12 months):

1. In the next 6~12 months, we will focus on the research and development and optimization of basic products: the construction and optimization of temperature-sensitive switches, the proof of concept in commercial strains such as Nissle, and the verification of export workability and efficiency of downstream applications.

2. Initial research and development based on the funds and experimental platform of the iGEM competition will be carried out until November; after the game, further optimization and commercialization of the results, as well as application in specific indications, will require 300,000 to 500,000 funds.

Long-term financial plan (5-10 years):

Our company's development is expected to go through the early stage of the technical platform construction, the mid-term market opening period, and the later stable development period. It is expected that the company will develop for 10 years before it starts to make profits.

The period is 5 years and the later period is 5 years. According to the development period, the funds we need are mainly used in different aspects. In the early stage, the funds required were mainly used for the construction of laboratory technology platforms and the development of basic products. The construction of the platform included the purchase of basic experimental equipment, the purchase of

experimental reagents and consumables, and the construction of technical lines. It is estimated that the initial funding requirement is about 2.5 million yuan; in the medium term, the funds required are mainly used to cooperate with iGEM's outstanding graduate/undergraduate team and 1-2 published research teams to launch more applicable microbial therapies. And help them enter the market. This stage does not consider hiring employees. It is estimated that the cooperation funds required in the medium term will be about 500,000;

Kim is mainly used to increase the visibility of the platform, hire company employees, and effectively collaborate with more researchers. Increasing the visibility of the platform mainly requires publicizing the company; hiring the company's employees includes paying employees' annual salary and basic welfare guarantees; the estimated cost of doing business cooperation with the research team is 400,000/team. The estimated cost in the later period is about 2.95 million yuan. In addition, every year, the maintenance of various types of equipment in the laboratory and the supplement of experimental reagents and consumables are required. It is estimated that it will cost 50,000/year. It is also necessary to continue the research and development of independent products and the optimization of the previous products. It is estimated to cost 200,000/year. .

The total is about 7.45 million.

## 5.2 Financial budget

It is expected that the company will develop for 10 years before it starts to make profits, including 5 years in the first half and 5 years in the later period.

In the later period, it is expected to employ 3 employees and conduct business cooperation with 3 research teams.

Development period	Specific issues	Required funds	Total funds /yuan
Early stage	Purchase basic experimental equipment	1.7 million	2.5 million
	Purchase experimental reagents and consumables	150000	
	Build a technical line	150000	
	Basic product development	500000	
Medium term	Collaborate with 1-2 iGEM teams and research teams with published results	500000	500000
Late (5 years)	Promote and promote the commercialization of the platform	50,000/year	250000
	Hiring employees (3 people)	100,000/year/person, ie 30 Million/year	1.5 million

	Business cooperation with various research teams	400,000/team	1.2 million (3 teams)
long	Maintenance laboratory equipment	50,000/year	500000
	Independent product development and pre-products	200,000 / year	1000000

	Optimization (late)		
total			7.45 million

### 5.3 financial analysis

In the first half of the year, the company was under construction and market opening. The expected profit was mainly from the cooperation of 1-2 iGEM teams and research teams. Because this stage is not for profit, it is expected to have a revenue of about 500,000 yuan. In view of the cost of 3 million yuan, there is no net profit; in the later stage of the company's establishment, the company has developed into a perfect commercial application platform, and has gained good reputation and popularity in the market, and will start to stabilize at this time. Cooperate with various researchers and collect profits, and at this time, the previous cooperation products have entered the market and are profitable. The profit model uses the sum of the initial deposit and the subsequent actual operating price. The initial deposit is 500,000 yuan. Once the deposit is signed, it will not be refunded, that is, regardless of whether the research team that cooperates with us will put its products into the market, we will have the minimum income guarantee. Another part of the profit will be priced according to the operation difficulty of the unit of the treatment engineering strain, called the unit price, and the total amount of the therapeutic engineering strains put into the market with the research team that we cooperate with is multiplied by the unit price. The total actual price of subsequent actual operations we can obtain. The amount of therapeutic strains for treatment of each scientific research team in the market is calculated according to the average level of market drug delivery. It is expected that we can obtain 2 million yuan of follow-up actual operations.

Make income. With a preliminary deposit, the revenue from commercial cooperation with each research team is expected to be 250.

Million. Based on commercial cooperation with 3 research teams within 5 years, the estimated total revenue is 7.5 million yuan. In the previous period, the estimated product revenue is 1 million/team. According to the previous guidance of two iGEM teams, the total revenue is 2 million. Based on the analysis of the profitability of the previous medium and mid-term, the total profit was 2.55 million yuan and the total profit rate

was 34%.The research team that cooperates with us can obtain profits from the products as soon as they are put on the market. The above calculated profit only considers the products entering the market for 3-5 years.

## **Chapter VI Risk Analysis**

### **6.1 Risk Identification**

If the market conditions are ideal, it is expected that after the relevant institutions such as fda have comprehensively determined the clear criteria for the application of microbial therapy to the market, microbial therapy will rapidly enter multiple parallel fields and take advantage. The universal platform developed by us can become an industry. The pioneers and pioneers in the field of intrinsic technology platforms, while laying a solid foundation for applicable microbial therapy, the practical therapies developed on the basis of our technology platform can also help our platform to be established in the market. Status.

The risks are mainly from the following aspects:

- 1 Our basic products cannot meet the therapeutic application standards established by institutions such as fda, which will increase the development cycle and costs, and the profit cycle will be lengthened, which may lose the first-mover advantage;
- 2 The treatments developed by our partners and partners have limited market recognition, occupying a limited market share and may have insufficient profitability;

### **6.2 Risk prevention and measures**

1. Strictly and fully optimize the basic products in the preliminary development preparation stage, fully understand the market demand and requirements, and fully prepare for the market's first-mover advantage;
2. Set up a rigorous review and screening system for the selection of collaborative projects, and consider hiring scientific consultants with practical experience to provide advice;
3. Continue to develop independent products, ensure the vitality of innovation, and gradually establish a complete industrial chain.

### 6.3 Venture capital withdrawal

1. Listing: If the company develops to a certain scale, you can consider the IPO direct listing, or indirectly through the shell-listed / backdoor listing;
2. Mergers and acquisitions: If the first-stage financing profit is not significant, then seek a new round of investment through the second phase of mergers and acquisitions, or consider being merged by large companies, talents, technology or knowledge industries are included in the large companies;
3. Bankruptcy liquidation: If the company's development is not good enough to recruit multiple rounds of financing or if there is no big company's willingness to acquire, then apply for bankruptcy liquidation