SUSTech-BIO

BUSINESS PLAN

Team Members

Name	**Role**
Yizhou Pan	Director of Entrepreneurship
Hengwei Su	Entrepreneurship Member
Qiya Zeng	Entrepreneurship Member
Yiduo Sun	Entrepreneurship Member
Tianci Yang	Entrepreneurship Member
Baolin Bai	Entrepreneurship Member

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1 Project Overview

Figure 1: Overview

This project targets a critical global public health challenge—fungal infections—by developing a **synthetic biology–based therapeutic platform** utilizing the **Type VI Secretion System (T6SS)**. The engineered bacterial therapy specifically eliminates WHO-designated *"critical priority"* fungal pathogens, including *Candida auris* and *Aspergillus fumigatus*.

The initiative aims to overcome the key limitations of existing antifungal treatments—**high resistance rates, severe toxicity, and limited R&D pipelines**—by delivering a **programmable, low-toxicity, and highly efficient therapeutic solution**.

Business Model

The project adopts a **dual-track model of innovative drug development and licensing collaboration**, operating under a **capital-light strategy** with the goal of accelerating **global market entry**.

R&D and Regulatory Strategy

The regulatory pathway prioritizes **efficient approval channels in both the United States and China:**

- **United States:** Leverage the FDA's *Accelerated Approval Pathway* for live biotherapeutic products, potentially exempting Phase III trials and reducing time-to-market by 2–3 years.
- **China:** Utilize the *Conditional Approval* mechanism (e.g., the Boao real-world data pilot program), allowing real-world studies to partially replace traditional clinical trials and enable faster domestic market access.

Licensing and Partnership Strategy

To mitigate financial and R&D risks, the project implements a **license-out cooperation model**:

- Out-license late-stage clinical development and commercialization rights to major pharmaceutical partners with global distribution networks.
- Secure milestone payments and sales-based royalties, with partnership intentions already established with **BGI Genomics** and **Bioin Biotech**, ensuring early-stage cash flow realization.

Market Strategy

A **"North America First, China Next"** dual-engine market strategy will be pursued:

- **North America as the primary launch market:** With a transparent regulatory framework and strong payment capacity (U.S. antifungal drug market projected at **USD 4.7 billion in 2024**), FDA approval will be prioritized.
- **China as the secondary market:** Leverage the *Hainan Medical Special Zone* policy to accelerate domestic rollout and reimbursement inclusion, achieving synergistic international market linkage.

Financing Plan

The financing roadmap aligns closely with R&D milestones and progresses through three stages:

- **Angel Round (RMB 80 million):** Supports strain optimization and preclinical toxicology studies.

- **Pre-A Round (RMB 50 million):** Initiates Phase I clinical trials (20–100 participants) to validate safety.
- **Series A Round (RMB 80 million):** Advances Phase II proof-of-concept clinical studies.

Funding allocation prioritizes **R&D investment (70%)** with the remaining **30%** dedicated to team development and regulatory compliance, ensuring optimal concentration of resources toward technology translation.

Strategic Summary

Through the integrated leverage of **policy advantages, capital acceleration, and strategic licensing**, this project establishes a high-efficiency pathway from laboratory innovation to global commercialization, driving the **T6SS-based antifungal therapy** toward becoming the next-generation breakthrough in infectious disease treatment.

2 Project Background

2.1 Burden of Fungal Diseases

- **Massive death toll:** Approximately 3.8 million people die from fungal diseases globally each year (Denning, *Lancet Infect Dis* 2024), surpassing malaria (0.61 million in 2022) and tuberculosis (1.4 million).
- **Causal attribution gap:** More than 60% of fungal-related deaths in low-income countries remain undercoded (GAFFI 2023), leading to systematic underestimation of the true burden.
- **Disease spectrum:** Invasive fungal diseases (IFD) cause 6.5 million annual cases with a 58.5% fatality rate; superficial fungal infections affect 1.3 billion people (WHO 2023), ranking third in prevalence after dental caries and tension-type headache.

2.2 Pathogen Spectrum

Among the over 600 fungal species capable of infecting humans, only 30 are responsible for routine diseases. These pathogens have co-evolved thermotolerance, enabling their growth at 37°C.

Three dominant pathogens are prevalent in clinical infections:

- **Candida species:** Account for 40% of bloodstream infections, with *Candida albicans* being the most common pathogen. Drug-resistant *Candida auris* strains have spread to 50 countries, posing a growing challenge to resistance.

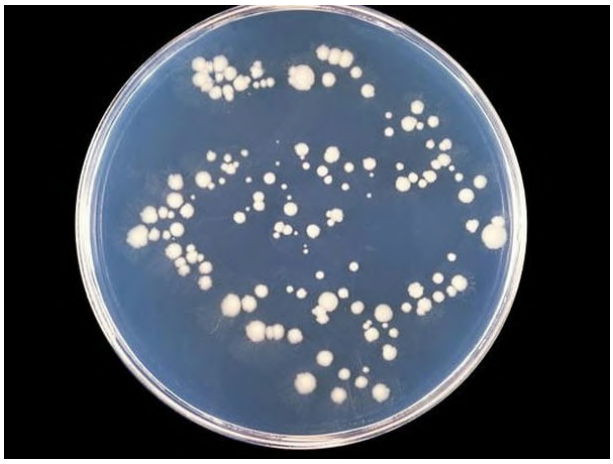


Figure 2: Candida species

- **Aspergillus species:** Account for 70% of pulmonary infections, with *Aspergillus fumigatus* responsible for 90% of invasive aspergillosis cases. In Asia, the resistance rate to azole antifungals has reached 20%.

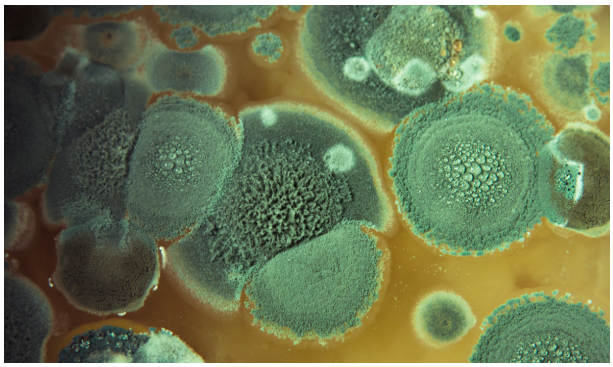


Figure 3: Aspergillus species

- **Trichophyton species:** Account for 80% of skin infections, with the global prevalence of onychomycosis rising to 15% (JAMA Dermatology 2023).

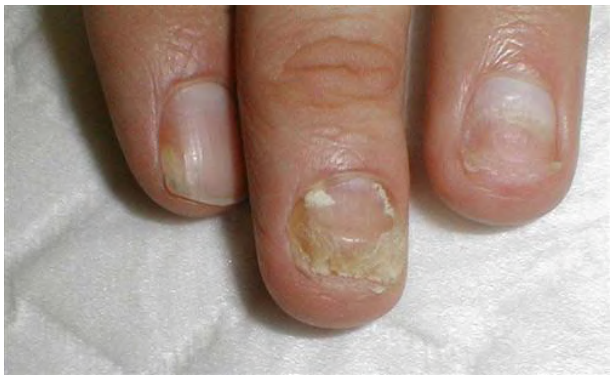


Figure 4: Trichophyton species

These figures indicate that the global prevalence and drug resistance of these three pathogens—particularly their resistance to conventional antifungal medications—have become significant public health challenges.

From the perspective of infection classification and clinical threat, invasive infections are highly lethal.

Indication	Annual incidence (10,000 cases)	Annual death (10,000 cases)	CFR	Core pain points
Candidemia	156.5	99.5	63.6%	The MDR rate of Candida auris is 42%, and the current echinocandin failure rate is high.
Chronic pulmonary aspergillosis	183.7	34.0	18.5%	Combined with tuberculosis/COPD, leading to poor long - term medication compliance.
Cryptococcal meningitis	19.4	14.7	75.8%	AmB cerebrospinal fluid penetration rate < 5%, with concurrent neurotoxicity and nephrotoxicity.
Total invasive infections	650.0	380.0	58.5%	58.5% of deaths are attributed to diagnostic delay or treatment failure.

Figure 5: Global Epidemiology and Core Clinical Challenges of Major Invasive Fungal Infections

2.3 Treatment Bottlenecks

1. **Drug Resistance:** *Candida auris* has been elevated to an ”emergency threat” by the U.S. CDC, with multidrug resistance rates reaching 42% in East Asia. This narrows the clinical window for the two mainstay antifungal agents, echinocandins and azole drugs. Aspergillus fumigatus resistance rates in Europe have risen to 20% due to sustained selection pressure from agricultural triazole pesticides, increasing treatment failure rates for standard itraconazole/voriconazole regimens and creating urgent demand for high-cost second-line oral and inhaled formulations.

2. **Depletion of Therapeutic Tools:** Systemic antifungal drugs are confined to four major classes—polyenes, azoles, echinocandins, and pyrimidine analogues. Only three new molecular entities have been approved over the past 20 years, with pipeline scarcity far exceeding that of antibiotics. Existing agents exhibit significant dose-limiting toxicities: amphotericin B causes nephrotoxicity in 49% of patients, while flucytosine induces myelosuppression in 25%. These limitations restrict optimal dosing, prolong hospital stays, and increase dialysis costs, creating a substantial market for less toxic novel therapies.

3. **Diagnostic Gap:** Only 12% of laboratories in low- and middle-income countries possess mycological testing capabilities (GAFFI 2023). Non-culture diagnostics (e.g., β-D-glucan, GM, PCR, MALDI-TOF) suffer from low penetration rates, contributing to 58.5% of invasive fungal disease deaths being attributable to delayed diagnosis or treatment failure. Once rapid POCT and companion diagnostics are included in medical insurance or centralized procurement, they can drive volume growth before drug market launch, creating a high-barrier ”water seller” market segment.

2.4 Global Policy Responses

In October 2022, the WHO released its inaugural *Fungal Priority Pathogens List (FPPL)*, marking the first inclusion of fungal infections within the global antimicrobial resistance (AMR) governance framework. The list explicitly identifies four categories of ”extremely high priority” pathogens: *Candida auris* (multidrug-resistant), *Aspergillus fumigatus* (azole-resistant), *Candida albicans* (fluconazole-resistant), and *Cryptococcus neoformans* (highly lethal CNS infections). The core significance of this list for the pharmaceutical industry lies in its potential to leverage policy to accelerate the concentration of capital and R&D resources toward these highly lethal, highly resistant fungal indications. This mirrors the impact of the 2017 WHO Priority Bacteria List for antibiotic R&D, offering new impetus for advancing research in these areas and potentially transforming the treatment landscape for fungal infections.

Consequently, fungal diseases have emerged as a global public health crisis on par with malaria and tuberculosis. However, systemic gaps remain in areas such as mortality attribution, new drug development pipelines, and diagnostic accessibility. Over the next five years, novel antifungal drugs—particularly those targeting the Gwt1, Hsp90, and Cdr1 pathways—combined with breakthroughs in rapid point-of-care molecular diagnostics, will be crucial in reducing the annual death toll of 3.8 million.

3 Pain Points of Existing Drugs

3.1 Drug Development

For decades, clinical practice has relied solely on four major classes of drugs (polyenoids, azoles, pyrimidines, and echinocandins), spanning over 60 years. From 2001 to 2023, only three novel mechanism drugs were launched (Ibrexafungerp, Olorofim, Rezafungin), while the WHO warns that 90% of drugs in development remain optimizations of existing targets. Only four classes of systemic antifungal drugs are clinically available, with a weak pipeline for new drug development.

3.2 Drug Defects

- **Polyene (1949–)**
  - **Representative:** AmB-d
  - **Critical Drawback:** Renal toxicity occurs in 49% of cases, driven by high-affinity binding of the drug to cholesterol in renal tubular epithelial cell membranes, subsequently activating the mitochondrial apoptosis pathway. Clinical data show approximately 30% of patients experience doubled creatinine levels, with another 30% facing dialysis risk.
  - **Clinical Outcome:** Forced treatment duration shortening and dose reduction directly elevate treatment failure rates by 15–20%.

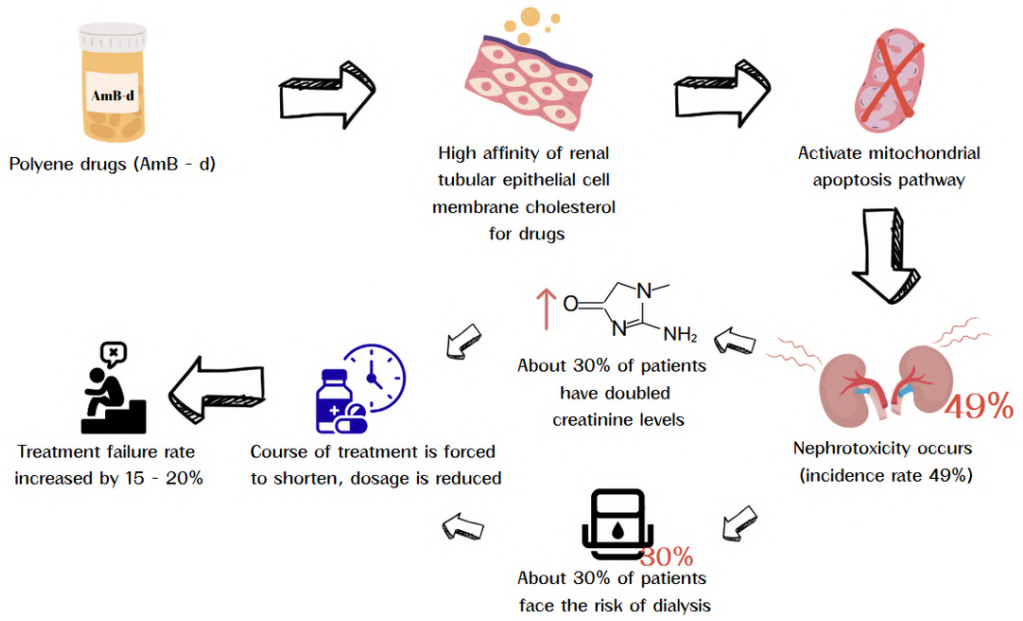


Figure 6: Drug Schematic Diagram

- **Azoles (1969–)**
  - **Representatives:** Fluconazole, Voriconazole
  - **Critical Drawback:** Triazole drugs significantly increase drug interaction risks through broad-spectrum inhibition of the CYP450 enzyme system. For example, voriconazole can increase tacrolimus C_max by approximately 3-fold. Since the triazole skeleton itself cannot circumvent this flaw, its use in transplant and ICU settings is significantly restricted.
- **Flucytosine Analogs (1968–)**
  - **Representative:** Flucytosine
  - **Critical Drawback:** Within 72 hours of monotherapy, FCY2 gene mutations rapidly drive up resistance rates. Clinically, forced combination therapy with amphotericin B (AmB) is often required. However, this regimen compounds bone marrow suppression (mediated by human cytidine deaminase), resulting in discontinuation rates of approximately 10–15% among patients.
- **Echinocandin (2001–)**
  - **Representative:** Candida

- **Fatal Limitation:** Zero activity against Cryptococcus and Mucorales, resulting in significant gaps in antimicrobial spectrum; lipopeptide structure precludes oral administration, restricting use to intravenous delivery in ICUs with limited accessibility.

Regarding pharmacokinetics, drugs like amphotericin B, voriconazole, and caspofungin exhibit distinct characteristics in parameters such as cerebrospinal fluid/plasma concentration ratios, leading to corresponding clinical consequences. Specific details are shown in the table below:

Drug	Cerebrospinal fluid/ plasma concentration ratio	Lung tissue/ plasma concentration ratio	Protein binding rate	Half - life (h)	Clinical consequences
Amphotericin B	<5%	0.3-0.7	>90%	24-48	Intrathecal injection is required for cryptococcal meningitis
Voriconazole	50%	2.5-4.5	58%	6-9	High neurotoxicity
Caspofungin	<1%	0.5-1.2	97%	9-11	Cannot treat CNS infections
Fluconazole	70-90%	1.0-1.5	11%	30	Poor biofilm penetration
Posaconazole	<10%	3.0-6.0	>98%	25-31	Food - dependent absorption

Figure 7: Drug Properties Summary Table

4 Market Size Forecast

4.1 Global Market Size

Forecasts from different sources:

Source	2025E	2030E	2034E	CAGR
Precedence Research	17.4	20.9	24.5	3.49%
Grand View Research	16.3	20.5	-	3.92%
The Business Research Company	29.7	-	41.8	9.00%
Mordor Intelligence	17.3	20.9	-	3.94%

Optimistic Estimate

2025E	2030E	2034E	CAGR
$2.97 billion	$3.50 billion	$4.18 billion	9.00%

Key Drivers:

1. Intensive launch of innovative drugs (e.g., Gwt1 inhibitors, chitin synthase inhibitors) gaining approval during 2025–2027 with peak sales reaching $4.5 billion
2. AI technology reducing preclinical R&D costs by 30% and improving conversion rates for small biopharmaceutical companies
3. Expanding healthcare coverage and rising out-of-pocket spending in emerging markets (China, India) driving 12% CAGR (2025–2034)

Conservative Estimate

2025E	2030E	2034E	CAGR
$1.726 billion	$2.09 billion	$2.45 billion	3.4% - 3.9%

Key Constraints:

1. Patent cliffs intensifying generic substitution post-2027, driving 5–7% annual price declines
2. Annual 1–1.5% increase in drug-resistant *Aspergillus* and *Candida* species impacting volume elasticity
3. Tightening reimbursement policies in developed markets reducing coverage standards by 3%

Risk Disclosure

1. **Clinical Failure Risk:** 30% failure rate in Phase II/III trials may reduce optimistic CAGR by 1.1 percentage points, delaying market launch
2. **Procurement Price Risk:** China's VBP policy projected to reduce global market by $130M by 2030 (55% price reduction)
3. **Resistance Outbreak Risk:** WHO restrictions on azole drugs may reduce conservative CAGR by 0.5 percentage points

4.2 Regional Market Size Analysis

2024 Base Year Market Conditions:

Region	2024 Scale (billion USD)	Global Share	Core Driving Factors	Main Obstacles
North America	55.3	44.50%	High prevalence + early - approved new drugs	Patent cliff, medical insurance price cuts
Europe	37.9	30.50%	High incidence of onychomycosis, OTC penetration	Volume - based procurement price cuts, stricter regulation
Asia - Pacific	20.1	16.10%	Population base, medical insurance expansion	Drug resistance, low - cost generic drugs
Latin America	6.7	5.40%	Government PPP, tropical climate	Payment capacity, counterfeit drugs
Middle East and Africa	4.4	3.50%	Unmet needs	Insufficient medical infrastructure

North American Market

Scenario	2025E	2030E	2034E	CAGR	Increment Logic
Conservative	56.8	64.1	68.9	2.20%	Patent expiration, 5% annual price decrease
Optimistic	58.9	70.4	81.7	3.80%	New target launch + biologic premium

- **United States (85% share):**
  - 2024E: $4.70B
  - Conservative: 25% sales decline post-2027 (generic entry)
  - Optimistic: $1.2B peak sales from new inhibitors (2026–2029)
- **Canada:** 3–4% annual price reductions, CAGR 0.5–1pt below US
- **Mexico:** 5–6% CAGR driven by out-of-pocket spending

European Market

Scenario	2025E	2030E	2034E	CAGR	Key Variables
Conservative	38.7	42.5	44.6	1.70%	Multinational centralized volume - based procurement
Optimistic	40.1	48	54.3	3.50%	Aging + Increase in deep fungal infections

- **Germany:** 2024E $890M; capped hospital budgets, 20% premium window from 2028
- **UK:** NICE HTA constraints; 30% price decline for generics from 2027

- **Eastern Europe:** 6% growth under optimistic scenario (echinocandin penetration)

Asia-Pacific Market

Scenario	2025E	2030E	2034E	CAGR	Incremental Drivers
Conservative	21.5	26.4	29.7	4.10%	Expansion of medical insurance catalog, generic drug substitution
Optimistic	24.3	37	47.5	9.70%	Introduction of innovative drugs + self - funded market

- **China:**
  - 2024E: $910M
  - Conservative: <3% growth (55% price cuts in procurement)
  - Optimistic: $1.67B by 2030E (domestic innovations)
- **Japan:** 2024E $470M; Conservative CAGR 1.6%, Optimistic 3.4%
- **India:** 2024E $380M; Optimistic CAGR 11%

Latin American Market

Scenario	2025E	2030E	2034E	CAGR
Conservative	6.9	8.1	8.9	3.20%
Optimistic	7.4	9.8	11.7	6.20%

- **Brazil (55% share):** SUS price pressure vs. private out-of-pocket growth

Middle East & Africa

Scenario	2025E	2030E	2034E	CAGR
Conservative	4.6	5.3	5.7	2.90%
Optimistic	4.9	6.5	7.7	6.50%

- **Gulf States:** High premium potential for innovative drugs
- **Sub-Saharan Africa:** Low-cost high-volume sales (GAVI subsidies)

5 Market Analysis

5.1 PEST Analysis

5.1.1 Political Analysis

- **Global Alliance for Health Security (2025):** G7 launched GARFA with $200M funding to support procurement of innovative antifungals in LMICs. China joined as founding member, enabling access through Belt and Road medical cooperation after WHO prequalification.
- **FDA Regulatory Breakthrough (2025):** "Streamlined Approval Pathways for Living Biological Therapy Products" exempts Phase III trials for topical therapies meeting:
  - >30% fatality rate for unmet needs
  - >80% cure rate in animal models
  - $<10^{-7}$ biological escape rate
- **Shenzhen Policy Support:**
  - 5B RMB national funding for synthetic biology
  - 830M RMB matching funds for Shenzhen Institute (2023)
  - 100% GMP rent reduction for first 3 years

Figure 8: Shenzhen Synthetic Biology Innovation Park

- **Hainan Boao Pilot Zone:**
  - Permits use of overseas-approved drugs (460+ introduced)
  - ”Lecheng R&D + Haikou Production” model accelerated 21 NMPA approvals
  - Dual 15% tax incentive (CIT & PIT)
  - 142M RMB biopharma R&D vouchers (2022)

5.1.2 Economic Analysis

- **Shenzhen Cost Innovation:** Shenzhen’s synthetic biology enterprises are driving a restructuring of biomanufacturing costs through foundational technological innovation. Some examples are as follows:

Company Name	Core Technology and Products	Cost Reduction and Impact
Senris Bio	Biosynthesis of Squalene (AI algorithms + automated yeast engineering)	First biosynthesis case in global pharmaceutical supply chain, reducing costs significantly within 3 years.
Huaxi Tang'an Bio	Non-animal sourced Heparin (enzyme-based synthesis of heparin)	Created the first non-animal sourced heparin production chain, shifting the industry to green bio-manufacturing, reducing material and environmental costs.
Zhongke Xinyang	Synthetic Ergothioneine (engineered bacteria, methanol as carbon source)	Shortened synthesis cycle by 24 hours, cutting glucose consumption by 28.5%, enabling cost-effective, green production.
Redlin Bio	Biosynthesis of Active Ingredients (enzyme-catalyzed peptide synthesis)	Reduced product costs from over 10,000 yuan/kg to under 2,000 yuan, with glutathione synthesis offering cost advantages.
Lanjing Microbe	PHA (Polyhydroxyalkanoate) Biobased Materials (Synbio OS™ R&D platform)	Lowered production costs of PHA products while improving degradation performance and user experience.

Figure 9: company name

Shenzhen’s cost reduction strategies primarily manifest across three dimensions:

- Enzymatic synthesis replacing animal extraction (e.g., heparin)
- C1 feedstock utilization (e.g., ergothioneine from methanol)
- AI-automation integration reducing enzyme modification cycles

These explorations demonstrate that synthetic biology has transcended isolated technological breakthroughs. By establishing a new closed-loop system integrating “technology-cost-supply chain,” it provides more economically viable and sustainable foundational solutions for innovative drug development.

- **Payment Innovations:**
  - China NHSA ”Pay-for-Performance”: 680 RMB/dose with ≥85% cure threshold
  - Gates Foundation ”Malaria-Fungal Joint Coverage”: $15/dose cap in Africa

5.1.3 Society Analysis

- **Primary Care Diagnostic Gaps (China CDC 2025):**
  - 63.5% fungal misdiagnosis rate (95% CI: 60.1–66.9%)
  - <12% diagnostic equipment coverage
  - 84.7% broad-spectrum antibiotic misuse
- **Candida auris Resistance:** 18.3% annual resistance gene increase (Nat. Ecol. Evol. 2025)
- **Drug Accessibility (Lancet 2025):**
  - 3.2B people facing shortages
  - Africa challenges: 81% cold chain failure rate, last-mile barriers
  - Engineered bacterial gel solution: stable at 55°C for 6 months, 37% lower production cost

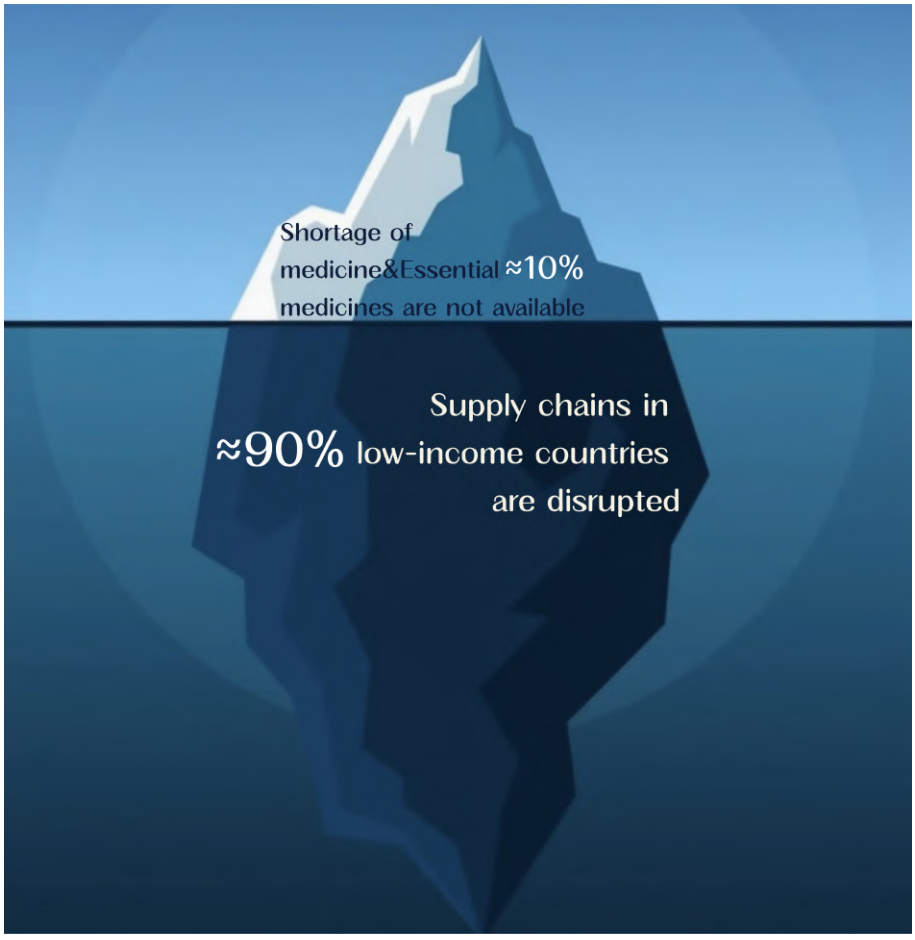


Figure 10: Iceberg Model

5.1.4 Technology Analysis

Core Advantages:

Technical Module	Innovation Point	Industry Breakthrough
T6SS Chassis Transplant	Recombinant introduction of core components of T6SS from Acidovorax citrulli into Escherichia coli BL21	For the first time, T6SS is realized to target and kill fungi, breaking through the limitations of traditional antifungal strategies and providing a more precise and efficient treatment method.
VgrG3 - RhsB Arsenal	VgrG3 acts as a "puncture needle" to recognize β - glucan of Candida auris, and RhsB acts as a "warhead" of nuclease to degrade fungal DNA.	Significantly improves killing efficiency and enhances antifungal effect.
Modular Weapon Platform	The VgrG3 - RhsB combination can be flexibly replaced to achieve rapid adaptation to new targets such as Aspergillus fumigatus.	Solves the bottleneck problem that the speed of drug resistance evolution exceeds that of drug research and development.

Figure 11: Technical Advantage

- Triple-precision control system:
  - pH-responsive promoter for targeted Hcp expression
  - Arabinose/blue light dual-switch suicide mechanism:
    - Survival only when *arabinose present* AND *blue light absent*
    - rhsB-induced death in other logic combinations

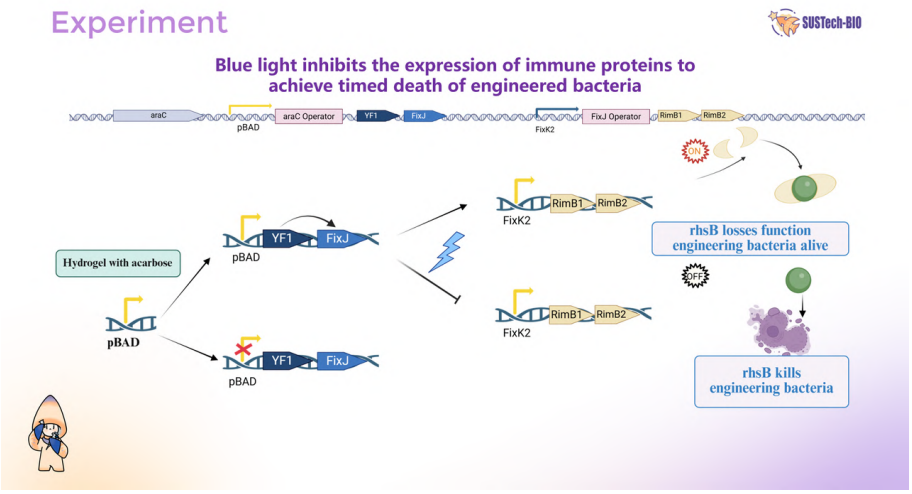


Figure 12: Suicide Factor

- Hydrogel-based precision delivery
- Gold medal in international synthetic biology competition
- Top ranking in China CCiC

Figure 13: Awards and Honors

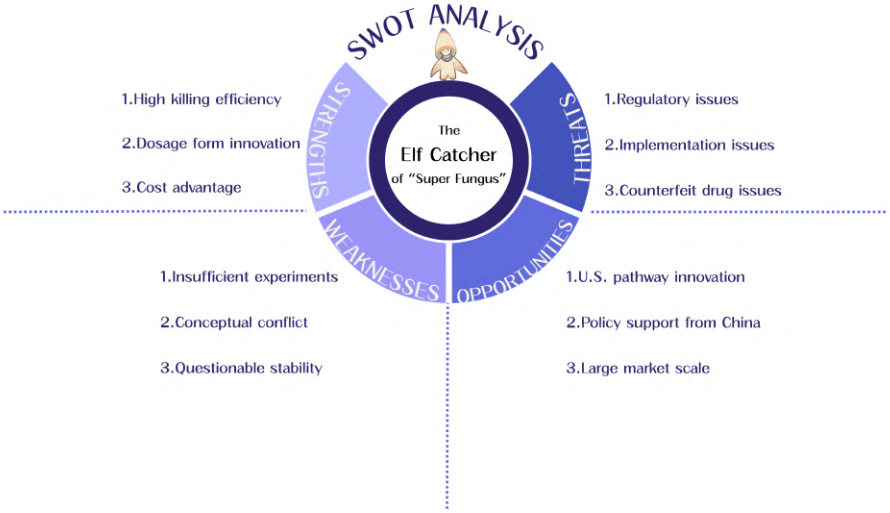


Figure 14: SWOT analysis

5.2 SWOT Analysis

5.2.1 Strengths

Internal:

- T6SS efficacy against *C. auris* with triple suicide switch
- Hydrogel formulation advantages
- 83% cost reduction vs chemical drugs

External:

- Shenzhen 120M RMB CDMO fund

- 100% GMP rent reduction
- IGBA collaboration platform

5.2.2 Weaknesses

Internal:

- Protein expression stability uncertainty
- Zero clinical trial data
- Physician skepticism toward live-bacteria therapy

External:

- Payment capacity disparities
- 63.5% primary care misdiagnosis rate

5.2.3 Opportunities

- WHO priority pathogen alignment
- FDA streamlined approval (2–3 year acceleration)
- $4.62B global treatment gap (WHO 2029)
- China's pay-for-performance pilot
- African Union $15/dose payment cap
- Rising AI diagnosis adoption in Asia

5.2.4 Threats

- Regulatory pathway complexity
- Science outreach operational challenges
- 17% counterfeit drugs in Eastern Europe
- Lack of FDA precedents
- Inadequate insurance coverage

6 Commercialization Path

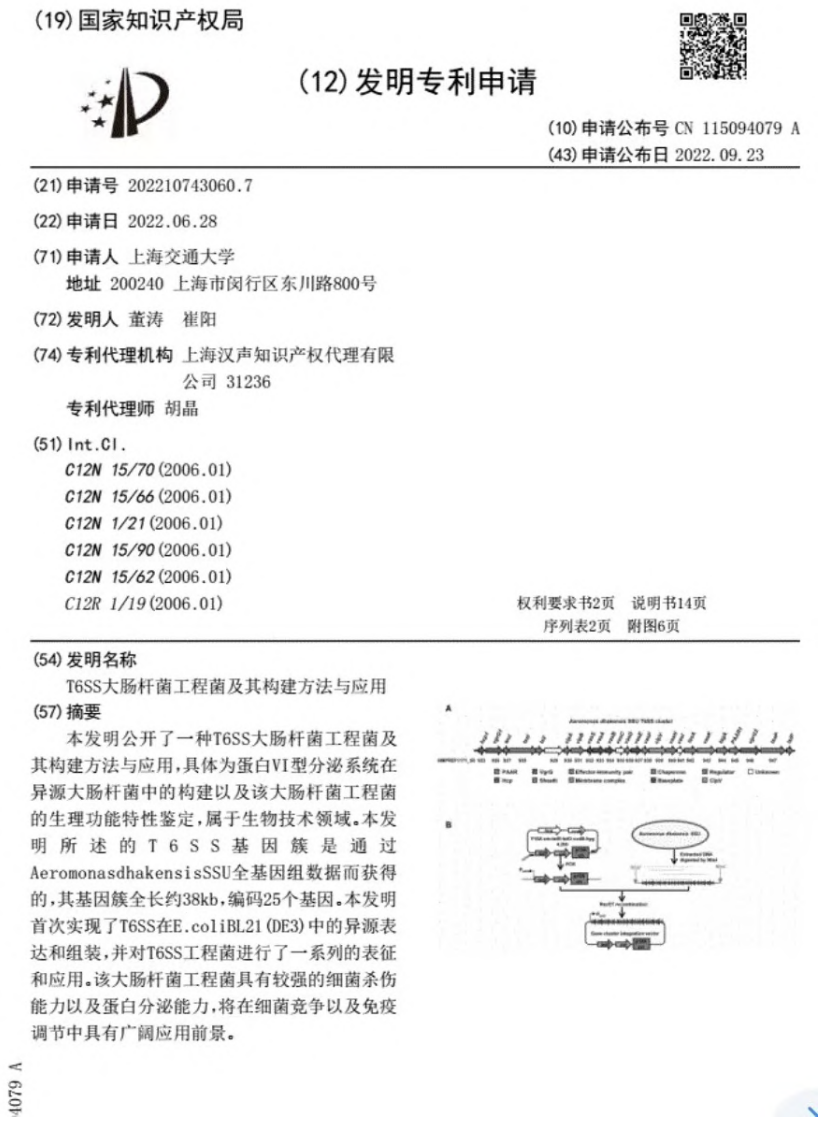
6.1 Protectability

The commercial success of T6SS is highly dependent on the protectability of its technology. Protectability is primarily achieved through intellectual property, confidentiality, and rapid market entry.

6.1.1 Intellectual Property Rights

Our team has filed a patent application with the China National Intellectual Property Administration for the construction and application of T6SS, as well as the technology for assembling T6SS into *E. coli*. We also plan to file a patent application in the United States to protect the core technology of T6SS.

Our team has completed the patent application for the core T6SS technology with the China National Intellectual Property Administration (CNIPA) (Application No.: CN202210743060.7). The application is currently undergoing substantive examination and is expected to be granted within 18 months through the accelerated examination pathway (in line with CNIPA's 2025 expedited processing target).



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(71) 申请人 上海交通大学
地址 200240 上海市闵行区东川路800号

(72) 发明人 董涛 崔阳

(74) 专利代理机构 上海汉声知识产权代理有限公司 31236
专利代理师 胡晶

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权利要求书2页 说明书14页
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(54) 发明名称

T6SS大肠杆菌工程菌及其构建方法与应用

(57) 摘要

本发明公开了一种T6SS大肠杆菌工程菌及其构建方法与应用，具体为蛋白VI型分泌系统在异源大肠杆菌中的构建以及该大肠杆菌工程菌的生理功能特性鉴定，属于生物技术领域。本发明所述的T6SS基因簇是通过AeromonasdhakensisSSU全基因组数据而获得的，其基因簇全长约38kb，编码25个基因。本发明首次实现了T6SS在E.coliBL21(DE3)中的异源表达和组装，并对T6SS工程菌进行了一系列的表征和应用。该大肠杆菌工程菌具有较强的细菌杀伤能力以及蛋白分泌能力，将在细菌竞争以及免疫调节中具有广阔应用前景。

Figure 15: Intellectual Property Rights

6.1.2 Confidentiality

In the field of biomedical innovation, maintaining technological confidentiality prior to patent approval is not only a legal requirement but also a matter of commercial survival, particularly in the highly competitive arena of engineered bacteria-based antifungal therapies. U.S. synthetic biology company Synlogic suffered a $120 million market share loss after its pilot plant leaked the chassis design of engineered bacteria, enabling competitors to launch products six months earlier (Nature Biotechnology, 2023). Based on this precedent, this project proposes establishing multiple layers of confidentiality measures:

Signing Entities	Confidentiality Measures
Core R&D Team	Sign technical confidentiality agreements
Production Partners	Conduct "black box" processing of data, only provide input and output parameters, shield process details, and need to sign technical confidentiality agreements
Investors	Disclose in segments and supplement key data after due diligence

Figure 16: Confidentiality Measures

When filing patent applications, replace structural details with functional descriptions to avoid directly disclosing the product's structure. Maximize the retention of technical secrets while satisfying the patent law's requirement for "sufficient disclosure." Simultaneously, introduce risk mitigation strategies, such as incorporating non-essential technical features (e.g., irrelevant gene fragments) into the specification to disrupt reverse engineering efforts by competitors.

The following is the confidentiality agreement signed with the company. The actual signed version is in Chinese, and an English translation is provided as a priority. Additionally, the version signed with BGI was based on a verbal commitment from the responsible party (with chat records), and an intern signed on their behalf.

https://static.igem.wiki/teams/5873/documents/entrepreneurship/confidentiality-agre
pdf

6.1.3 Rapid Market Launch

Given that core technology patents typically offer only 20 years of protection (from the filing date), and valuable market exclusivity is significantly eroded by lengthy R&D and regulatory approval processes, teams must adopt every feasible strategy to aggressively compress the timeline from laboratory to market. This requires efficiently advancing preclinical studies (pharmacology, toxicology, CMC, etc.) and phased clinical trials (Phase I safety, Phase II efficacy, Phase III large-scale validation) in parallel, while ensuring scientific rigor and patient safety. Delays at any stage of R&D translate to substantially reduced commercial returns within the patent protection period. Therefore, establishing agile decision-making processes, optimizing resource allocation, and proactively adopting innovative approaches like adaptive clinical trial designs are critical. The goal is to bring T6SS-based innovative therapies to market as early as possible before patent expiration.

To overcome the high R&D costs, complex manufacturing challenges, and formidable market

access barriers common in biopharmaceuticals, the team must proactively seek strategic partnerships with large pharmaceutical companies during early development stages—even before key clinical data emerges. The core objectives of this approach are twofold: first, to ensure that these key potential partners—possessing substantial capital, global channels, and mature commercialization systems—develop strong interest and confidence in the unique value and market potential of the T6SS platform through data sharing and scientific exchange; second, to expedite the conclusion of licensing-out agreements. Successful early licensing not only provides crucial non-dilutive funding for subsequent R&D but also accelerates clinical trials, resolves large-scale production challenges, and efficiently expands global markets by leveraging partners' extensive experience and resources. This maximizes the commercial value of T6SS technology while jointly sharing risks and returns.

6.1.4 Disclaimer

Although the team proactively consulted legal experts prior to the competition and implemented necessary preliminary measures (such as internal confidentiality agreements and document encryption) to protect its core technology, the inherent time constraints of the patent application process (typically requiring months or even years for examination) combined with the competition's urgent timeline ultimately prevented the team from obtaining patent authorization or entering substantive examination before the official competition commenced. Faced with this practical constraint, the team made a strategic decision after careful evaluation: to publicly disclose certain key technical details during the competition. Recognizing the potential disclosure risks associated with this competition, the team will immediately initiate the patent application process. It will systematically submit the innovations demonstrated during the competition and subsequent optimization results for application, striving to establish legal protection as soon as possible. For any subsequent in-depth technical discussions with external entities (including potential investors, partners, suppliers, etc.), the team will strictly require the signing of legally binding non-disclosure agreements (NDAs). These agreements will clearly define the scope of confidential information, obligations, duration, and consequences of breach, rigorously controlling the circulation and usage of sensitive information.

6.2 Value Chain Analysis

In the pharmaceutical and clinical research industry, the entire process from drug conceptualization to its eventual delivery to patients involves multiple critical stages. These stages collectively form a complete value chain, as detailed below:

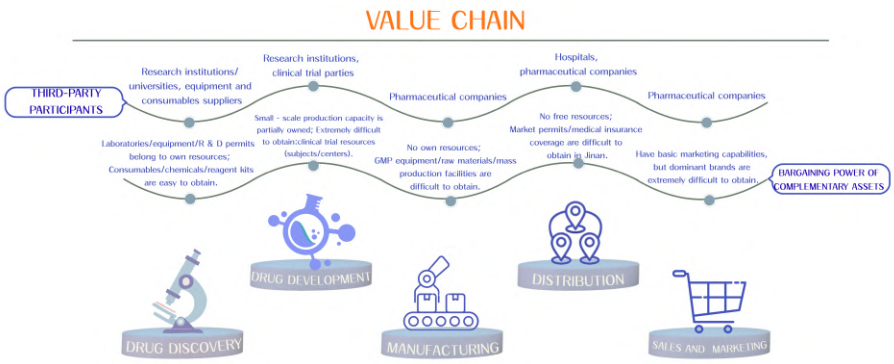


Figure 17: Value Chain

T6SS is currently in the "drug development phase," focusing on drug discovery and partial drug development. During the drug discovery stage, the team possesses laboratories, equipment, and licenses but requires collaboration with research institutions. For the drug development stage, the team needs additional laboratory facilities and clinical trial resources, which are scarce and costly. As for production/manufacturing, distribution, and marketing, these stages necessitate pharmaceutical companies' production equipment, market channels, and marketing networks.

6.3 Commercialization Strategy

Based on value chain analysis, we have decided to focus on drug discovery and certain drug development stages, while licensing out subsequent development and commercialization activities to large pharmaceutical companies.

6.3.1 Commercialization Strategy Environment

Through discussions with Mr. Wang Guan'en of Hongxun Bio, we understand that this project currently operates within a typical "Ideas Factory" environment. While demonstrating strong technical capabilities—the team has successfully established an engineered bacterial gel technology platform achieving three major innovations—it lacks complementary assets, specifically manifested in:

- Insufficient mass production capacity: Protein expression stability has not undergone GMP batch validation, posing risks to mass production processes
- Lack of clinical data: No animal model or human trials have been conducted, resulting in insufficient full-stage clinical data to support regulatory approval.

- Market access barriers: Low acceptance of "microbiome-based" therapies among primary care physicians in China, coupled with inadequate commercial infrastructure such as healthcare insurance integration and distribution channels.

Therefore, while our team possesses disruptive technology (with validated technical feasibility), we lack the "complementary assets" required to bring the product to market—including scaled production, clinical trial management, regulatory submission expertise, distribution networks, and physician education systems. Large pharmaceutical companies hold the core complementary assets needed for this project, making collaboration the essential path for commercializing the technology.

6.3.2 Partners and Resources

Through deep integration with core nodes in the industrial chain, our team fully leverages the cluster effect and geographical advantages of Shenzhen Synthetic Biology Industrial Park. Frequent interactions with Shenzhen Guangming Biosynthetic Industrial Park have enabled us to establish a multi-tiered, multidimensional collaborative framework.

Figure 18: Partners

The partners within this system span all key sectors of the industry, specifically encompassing the following primary categories:

- **R&D Phase:** Shenzhen University of Science and Technology, Sun Yat-sen University (Shenzhen), Shenzhen Bay Laboratory, Shenzhen Medical Academy, National Bio-Manufacturing Industry Innovation Center, Shenzhen Engineering Biology Industry Innovation Center

- **Upstream Technology Platforms:** Saiqiao Bio, Dibei Intelligent Technology, Zhenhe Intelligent Manufacturing, Zhongke Lingtan
- **Midstream R&D and Manufacturing:** Sailu Medical, Lingfu Top Bio, Boyin Bio, Shenzhen Xigia Biotechnology, Shenzhen Runming Biotechnology
- **Downstream Applications and Products:** Aonu Medical, Aoli Bio, Shenzhen Ningju Bio-New Materials Technology Co., Ltd.

The team will share expertise, clinical data, laboratory equipment, biological tissues, and other resources, leveraging partners' high-value laboratory facilities and clinical research capabilities.

6.3.3 Commercialization Steps

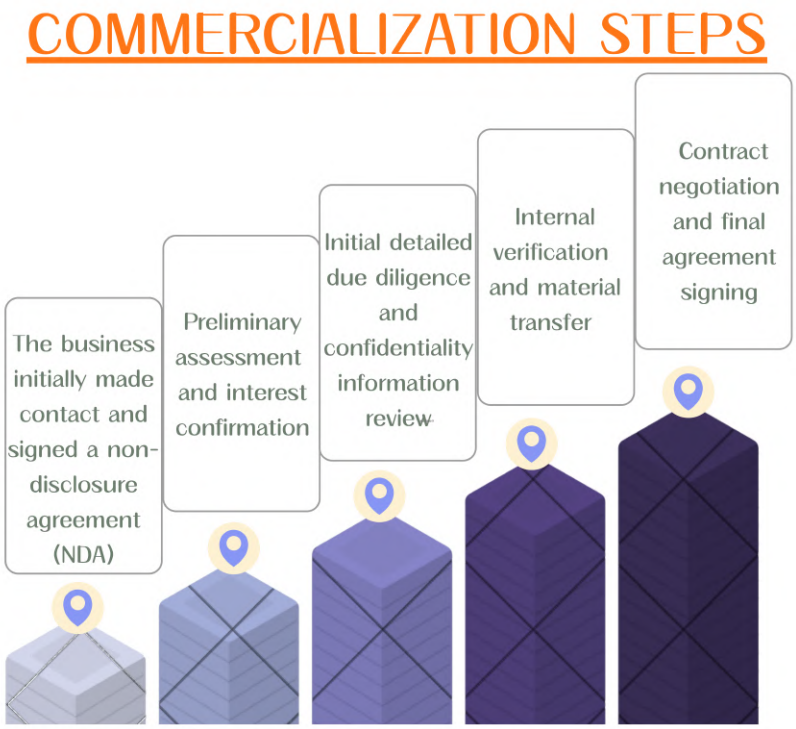


Figure 19: Commercialization Steps

1. **Initial Engagement and Non-Disclosure Agreement (NDA) Signing**
   To advance the commercialization of the T6SS project, the team establishes preliminary contacts with potential large pharmaceutical companies, presenting an overview of the project, its technological advantages, market potential, and preliminary results. Upon reaching a cooperative intent, both parties sign a Non-Disclosure Agreement (NDA) to protect the project's core technology and commercial secrets. Subsequently, the team

provides non-confidential materials such as technical summaries, publicly available data, and proof-of-concept data to assist the pharmaceutical company in evaluating the project and laying the groundwork for deeper collaboration.

2. **Preliminary Evaluation and Interest Confirmation**
   Upon receiving the non-confidential materials, the pharmaceutical company organizes a specialized team to conduct a preliminary assessment of scientific, strategic, and market fit, reviewing the technical summary, public data, and proof-of-concept results. If the assessment is positive, the pharmaceutical company will request a more detailed Confidential Information Package (CIP), marking the transition to a deeper stage of collaboration. The team must prepare a CIP containing technical details, R&D plans, market analysis, and commercial applications for the pharmaceutical company's further evaluation and decision-making.

3. **Detailed Due Diligence and Confidential Information Review**
   Upon receiving the team's Confidential Information Package (CIP), the pharmaceutical company's cross-functional team will conduct in-depth technical due diligence on its detailed contents.

4. **Internal Validation and Material Transfer**
   If the due diligence results are positive, the pharmaceutical company will typically request internal validation experiments. To facilitate this, both parties will sign a Material Transfer Agreement (MTA) specifying the transfer of T6SS samples, scope of use, intellectual property ownership, confidentiality obligations, and terms for sample return or destruction. Subsequently, the pharmaceutical company will conduct critical validation experiments on T6SS within its own laboratory environment, as stipulated in the agreement, to confirm whether its core performance aligns with the data provided by the team.

5. **Contract Negotiation and Final Agreement Signing**
   After reaching consensus on the Term Sheet and entering the exclusive negotiation period, both teams engage in formal contract negotiations. The core of these negotiations centers on the specific terms of the final cooperation agreement.

7 Development Strategy

7.1 STP Analysis—Segmentation

Given the varying policy environments across different countries and regions, this paper segments the pharmaceutical market into major regions including North America, Europe, and Asia-Pacific. Policies in each region exhibit significant differences in market access, drug pricing, and health insurance reimbursement, with these variations exerting differing impacts on commercial launch strategies for pharmaceutical products.

7.1.1 North American Market

Taking the United States as an example, policies in this region provide significant support for pharmaceutical R&D and market access. The U.S. government has designated *Candida auris* as an ”emergency threat” and included innovative drugs such as novel triazoles and echinocandins in Medicare coverage, ensuring patient access to cutting-edge treatments. Concurrently, the FDA accelerates drug approval processes through multiple measures to support the rapid market entry of innovative medications.

Specifically, the FDA implements multiple accelerated approval policies, including:

1. **Accelerated Approval:** For drugs treating serious or life-threatening conditions that address unmet medical needs, the FDA permits approval based on surrogate or intermediate clinical endpoints, subject to post-approval studies to validate actual clinical benefit.
2. **Fast Track designation:** Companies may negotiate with the FDA to use a rolling review process for drugs with therapeutic potential that address unmet medical needs, accelerating the approval process.
3. **Priority Review designation:** Drugs demonstrating significant advantage receive FDA review within six months.
4. **Orphan Drug designation:** Drugs for rare diseases qualify for incentives such as tax credits.
5. **Qualified Infectious Disease Product Review:** Antibacterial or antifungal drugs treating serious or life-threatening conditions qualify for priority review and fast track designation.

The FDA also requires drugs approved under accelerated pathways to undergo post-marketing studies to confirm safety and efficacy. Pharmaceutical companies must submit periodic progress reports; if results fail to demonstrate clinical benefit, the FDA may take appropriate actions. This policy framework balances expedited market access with safeguarding drug safety and efficacy, ensuring patients benefit early from innovative medicines while protecting public health.

According to the annual new drug approval report released by the FDA's Center for Drug Evaluation and Research (CDER), the agency approved 55 innovative drugs in 2023. Among these, 65% utilized accelerated development and review pathways, with 25 drugs designated as Fast Track candidates.

Overall, the North American market provides substantial policy support for new drug R&D and commercialization, enabling relatively swift completion of new drug approval processes.

Comparison of Three Policies for Accelerating the Review and Approval of New Drugs in the United States

PROJECT	Year of Issuance	Legal Basis	Conditions	Evaluation Basis
Conditional Approval	1992	Prescription Drug User Fee Act (PDUFA)	Treats serious diseases, and the drug has significant advantages compared with existing therapies	Reasonably predictable clinical benefits, non - fully verified surrogate endpoints or intermediate endpoints
Priority Review	1992	Prescription Drug User Fee Act (PDUFA)	Treats serious diseases, and the drug significantly improves safety and/or efficacy	Safety and/or efficacy data
Breakthrough Therapy	2012	Food and Drug Administration Safety and Innovation Act (FDASIA)	Treats serious diseases, the indication has potential unmet clinical needs, and the drug has significant advantages compared with existing therapies	compared with existing therapies Preliminary clinical data

Figure 20: comparsion of three policies-north american

7.1.2 European Market

In Western Europe, particularly France and Germany, the pharmaceutical market demonstrates significant advantages due to high per capita healthcare spending and abundant medical resources. Both countries have achieved per capita healthcare expenditures reaching thousands of dollars and boast high physician density, providing a solid foundation for rapid new drug launches and health insurance coverage. For instance, after the launch of long-acting echinocandin drugs, full health insurance coverage was achieved within just three months. Simultaneously, real-time connectivity with the European Centre for Disease Prevention and Control (ECDC), combined with surveillance through the Antimicrobial Resistance Network, enables effective tracking of fungal transmission, such as *Candida auris*.

However, in Eastern Europe, centralized procurement policies driving down prices have created significant bottlenecks in drug supply. Poland, for instance, experienced two shortages of liposomal amphotericin B in 2023. Despite sufficient hospital beds, issues like outdated equipment and electronic prescription coverage below 50% substantially increased patient wait times for new drugs. Polish patients typically face waits of 2 to 3 years to access equivalent new medications. At the EU level, drug approval and market access policies primarily utilize four

”fast-track” mechanisms for accelerated review:

1. **PRIME Priority Medicines designation:** Aims to provide priority review for clinically urgent drugs.
2. **Accelerated assessment:** Shortens the review cycle by 60 days to rapidly respond to market needs.
3. **Conditional Marketing Authorization:** Permits drugs with incomplete data but demonstrated significant benefits to enter the market, typically requiring supplementary data post-approval.
4. **Special Use Authorization:** Allows special approval procedures for rare diseases or public health emergencies where obtaining complete clinical data is exceptionally difficult.

Comparison of Four Policies for Accelerating the Review and Approval of New Drugs in the European Union

PROJECT	Year of Issuance	Legal Basis	Conditions	Evaluation Basis
Conditional Approval	2005	Article 14(7) of EU Regulation 726/2004	Drugs for emergency use in situations seriously endangering life, orphan drugs; there must be unmet clinical needs	Incomplete data, and the possibility of collecting additional data before marketing approval is low
Accelerated Review	2005	Article 14(9) of EU Regulation 726/2004	Drugs that serve major public health interests, especially innovative drugs	Applicants need to prove compliance with'major public health interests'
PRIME Channel	2016	Article 14(9) of EU Regulation 726/2004	Drugs that serve major public health interests and have unmet medical needs	Preliminary clinical data
Exceptional Approval	2004	Article 14(8) of EU Regulation 726/2004	Drugs for emergency public health needs	Incomplete non - clinical and clinical data, and the possibility of obtaining completeness is extremely low

Figure 21: comparsion of three policies-european

Similar to the U.S. FDA, these four accelerated review pathways in the EU can be complementary, meaning a new drug can utilize multiple accelerated approval routes simultaneously. However, compared to the U.S., the EU exhibits greater conservatism in implementing accelerated approvals. Constrained by its relatively loose organizational structure and internal coordination challenges, the EU tends to be more cautious in recognizing accelerated approvals for new drugs. The advancement of approval procedures is typically conservative and subject to certain administrative constraints.

Overall, Western European markets demonstrate high efficiency and flexibility in timely drug market access and health insurance coverage, particularly in France and Germany. Eastern Europe, however, faces longer drug waiting times and supply bottlenecks due to budget constraints and resource allocation challenges. While the EU’s accelerated approval policies offer multiple pathways to expedite new drug launches, their implementation is constrained by coordination efficiency, resulting in relatively slower approval speeds.

7.1.3 Asia-Pacific Market

The Asia-Pacific market, represented by China, India, Japan, and South Korea, exhibits significant variations in drug approval and market access.

China Market As primary healthcare standards improve, particularly in township areas, the potential of the pharmaceutical market is gradually being unlocked. However, misdiagnosis rates in these areas remain a major challenge. For instance, the misdiagnosis rate for invasive aspergillosis remains as high as 58% due to the lack of G/GM testing. This highlights the weakness of primary healthcare facilities in accurate diagnosis, which impedes the timely and appropriate use of drugs. Nevertheless, with the advancement of China's healthcare reforms and the improvement of primary diagnosis capabilities, the market potential remains substantial.

On the policy front, China implemented conditional approval policies starting in 2017 and introduced a breakthrough therapy designation program in 2020. These initiatives accelerated the drug approval process. In 2024, China launched the "front-end service" pilot program, reducing the IND review cycle for innovative drugs to 21 days and significantly shortening their time to market. Additionally, the implementation of medical insurance coverage or price negotiation mechanisms helps balance procurement pressures, making it easier for innovative drugs to enter the market and gain patient acceptance.

Indian Market India accounts for approximately 30% of global antifungal generic drug exports but faces challenges with cold chain transportation gaps, leading to instability during transit for products like posaconazole suspension. To address this, Indian pharmaceutical companies such as Cipla have established regional cold chain centers and developed thermostable tablets to overcome cold chain bottlenecks. The primary challenges in the Indian market lie in logistics and supply chain management, particularly for temperature-sensitive drugs where cold chain infrastructure is critical.

Japan and South Korea markets The Japan and South Korea markets excel in medical technology application. Leveraging AI-CT technology, Japan and South Korea have successfully increased the detection rate of pulmonary aspergillomas to 92%, significantly improving early diagnosis efficiency. However, despite significant technological advances, drug accessibility faces substantial cost pressures. Japan's high cost thresholds and South Korea's 30% out-of-pocket copayment for high-cost drugs notably slow new drug adoption far behind technological advancement. These policy and cost structure constraints limit patient access to medications, hindering rapid market growth.

In summary, countries in the Asia-Pacific region have adopted different strategies to address varying challenges in their pharmaceutical markets. China has enhanced drug accessibility through policy reforms, India has demonstrated strong innovation capabilities in addressing cold chain logistics, while Japan and South Korea lead in applying advanced medical technologies. However, the adoption of new drugs remains relatively slow in these countries due to high-cost policies and high patient copayment rates. Overall, pharmaceutical innovation and distribution in the Asia-Pacific market face multiple challenges spanning technology, policy, and infrastructure. Effective measures across these domains are needed to accelerate drug accessibility and utilization.

7.2 STP Analysis—Targeting

China's drug approval process lags behind that of the United States and the European Union. Data from 2017 shows that China's median standard review duration was 670 days, compared to 310 days in the U.S. and 380 days in the EU. For accelerated review, China's median duration was 425 days, versus 230 days in the U.S. and 208 days in the EU. Although the U.S. and EU have progressively shortened review timelines through workflow optimization, technical guidance issuance, and clear regulatory requirements, China lags behind in this regard—particularly without accelerated review policies for new drug clinical research phases.

Furthermore, China's review policies appear less clear and systematic compared to those of the US and EU. By 2019, China had issued only 194 guidance documents, whereas the FDA released approximately 1,223 guidance documents by February 2018, clearly demonstrating the gap in policy support and transparency between the two.

Therefore, from the perspective of regulatory maturity and policy support, the U.S. and EU markets are the preferred target markets. This is particularly true in the field of invasive fungal diseases, where the incidence rate in the U.S. is significantly higher than in many European countries, and the market's payment capacity is more mature. The U.S. sees approximately 75,000 cases of invasive aspergillosis annually, while ICU-acquired candidemia carries a mortality rate of 30%-60%. This backdrop creates substantial market demand and development opportunities for novel therapeutics.

Nevertheless, discussions with Mr. Liu Naibin of Hongxun Biotech revealed that China's regulatory environment offers certain advantages forenterpreenterprises. Being based in China allows our team to adapt more swiftly to local policy changes and engage more directly with government departments and relevant agencies. This enables better management of potential risks, making it an excellent choice for the initial phase.

Based on the above considerations—balancing regulatory efficiency, policy clarity, and disease burden—we have decided to target the North American market as our primary focus, positioning China as a secondary market for preliminary trials. We plan to pursue conditional approval pathways for rapid market entry, aiming to establish an initial foothold in the domestic market. This will form a dual-track strategy of "Asia-Pacific pilot followed by Europe-US volume expansion," leveraging both local policy and market advantages while utilizing the mature regulatory frameworks and payment capabilities of the European and American markets to drive global drug promotion.

7.3 STP Analysis—Positioning

Based on the above target market selection, our team will concurrently advance drug approval processes in China and the U.S. The specific development strategy is as follows:

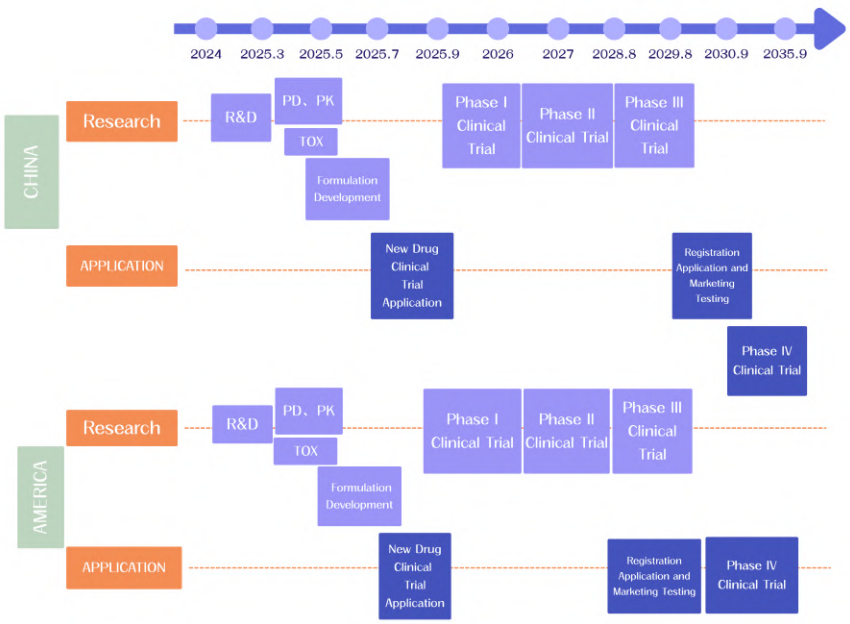


Figure 22: Future Schedule

In accordance with NMPA requirements for new drug market approval, the following China market development strategy is established: Following completion of engineered microorganism process optimization in March 2025, animal efficacy, toxicology, and formulation development will be finalized within two months. An IND submission will be made in July 2025, with Phase I clinical trials (six months, 20-100 healthy subjects) commencing after 60-day review approval. This will be followed by Phase II (one and a half years) and Phase III (two years), with

a maximum patient cohort of 2,000 subjects. In September 2029, following the final data lock of Phase III, the company will submit a Biologics License Application (BLA) to the NMPA. Utilizing the 12-month standard review period, approval for market launch is targeted for September 2030. Concurrently, a five-year Phase IV validation study will commence, ensuring seamless integration between R&D, regulatory submission, and post-marketing surveillance.

7.4 Marketing

7.4.1 Marketing Objectives

Our marketing objectives primarily encompass the following areas: First, enhancing brand recognition for both the licensor and ourselves to establish a position of trust within the industry and community. Second, disseminating relevant knowledge to healthcare professionals and providing in-depth information about the diseases we treat. Additionally, we plan to educate patient groups (such as the Vasculitis Foundation) about innovative cell therapies. Following drug launch, we must continuously disseminate critical information—including side effects and treatment efficacy—to ensure the public receives timely updates. By enhancing website visibility and defining key action steps for marketing ROI, our ultimate goal is to maximize investment returns through increased sales driven by pharmaceutical companies.

7.4.2 Marketing Strategy

We recently interviewed Chenmu Interactive, one of the leading companies in Xiaohongshu marketing. This in-depth exchange provided comprehensive insights into current Xiaohongshu marketing models. Chenmu Interactive employs a "four-pronged" integrated marketing strategy, centered on enhancing brand exposure and conversion rates through multi-dimensional collaboration. Specifically, these four strategies include:

1. **Account Management:** The foundation of marketing, ensuring consistent content updates and high user engagement through meticulous brand account operations. Chenmu Interactive leverages professional content planning and data analysis to help brands build long-term influence and follower bases on Xiaohongshu.

2. **Soft Product Placement:** Collaborating with platform influencers and bloggers to subtly integrate products or services into everyday shares and experiences, naturally sparking user purchase intent. Through precise brand positioning and content creation, Chenmu Interactive enables brands to achieve effective product recommendations.

3. **Influencer Sales:** By forging deep partnerships with Xiaohongshu KOLs (Key Opinion Leaders) or internet celebrities, brands leverage their strong fan following for direct product promotion. Influencer sales rely not only on creative and compelling content but also on precise market positioning and fan engagement to maximize conversion rates.

4. **Ad Distribution:** Beyond organic content recommendations and influencer collaborations, ad distribution precisely delivers brand messages to potential users through Xiaohongshu's advertising system. Chenmu Interactive optimizes ads and implements targeted placements to rapidly boost brand exposure and clicks, driving sales conversions.

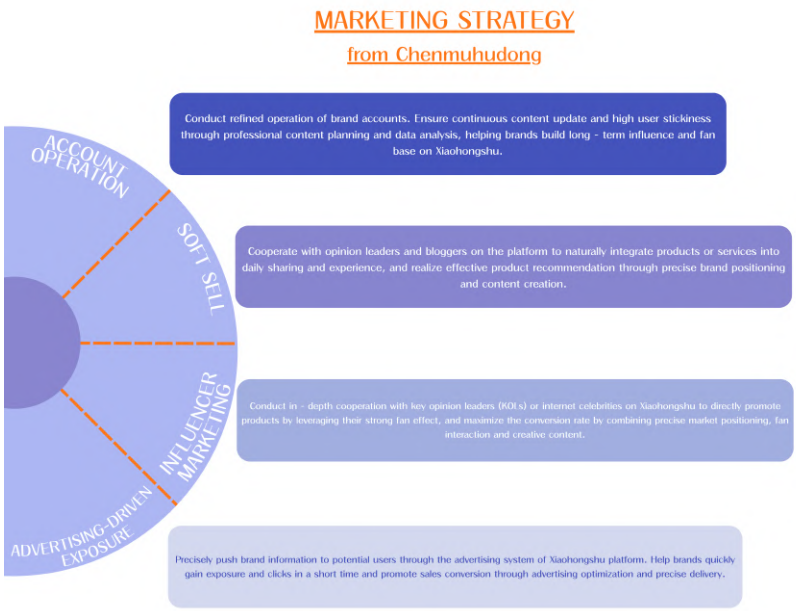


Figure 23: Martketing Strategy

Regarding pricing, Chenmu Interactive offers a transparent and targeted structure. Specifically, they provide distinct service packages: Account management costs 50,000 for six months, covering daily operations, content updates, and data analysis. For integrated services encompassing soft promotion, influencer collaborations, and ad distribution, they offer a comprehensive annual package priced at 500,000. This package delivers comprehensive support across all three services, encompassing influencer collaborations, ad distribution, and integrated soft marketing execution. This ensures brands achieve thorough and impactful market coverage on Xiaohongshu.

Following thorough internal discussions and evaluations, we have decided not to procure third-party marketing services prior to the clinical trial phase. We will leverage our proprietary platforms—including our official WeChat account, Xiaohongshu, and Instagram accounts—for

initial publicity and brand promotion. Upon entering the clinical trial phase, we will consider introducing professional marketing services based on project progress and market demand to further enhance brand exposure and market penetration.

8 MVP

8.1 MVP Design

MVP (Minimum Viable Product) refers to a product prototype developed in the early stages of product development that satisfies user needs with the most fundamental and core features. The core concept of MVP is to launch a product with minimal functionality early on—sufficient to validate market demand—testing product hypotheses at the lowest cost and in the shortest time possible. This approach facilitates rapid collection of user feedback, identifies product pain points and opportunities, and enables iteration and optimization.

The key advantage of an MVP lies in its ability to prevent overdevelopment and resource waste, ensuring teams can validate market demand and user response before full product launch. Through an MVP, companies can identify potential issues early, avoiding excessive investment in features that fail to meet market needs. Additionally, an MVP enables low-risk market entry, allowing for gradual refinement of product functionality and increased success rates. Consequently, it plays a crucial role in entrepreneurship and product development, particularly in high-uncertainty market environments.

During the MVP design phase, we consulted Professor Wu Decheng, Chair Professor at Southern University of Science and Technology. By applying our product and mainstream Candida auris fungicides to Candida auris culture plates at equal concentrations, incubating them, and comparing their efficacy, this design proved both straightforward and capable of validating product effectiveness at minimal cost and maximum speed. This approach effectively avoids overly complex experimental procedures, ensuring valuable feedback is obtained during the initial stages.

8.2 Verification of Results

We evaluate the MVP's outcomes through two key dimensions: First, by assessing the product's effectiveness to validate its core functionality, ensuring it delivers expected results in the experimental environment. Second, by securing letters of intent from interested stakeholders to demonstrate the product's appeal and potential commercial value in the real market. This dual-

pronged validation not only showcases the product's functionality but also confirms its market fit within the industry, laying the groundwork for future promotion and partnerships.

8.2.1 Test results

Experimental Overview

This report analyzes and summarizes the killing efficiency of different killing agents (wild-type/mutant Candida acida, amorolfine hydrochloride, ketoconazole) against the prey organism Candida auris under co-culture conditions at 28°C for 5 hours across three independent experiments.

T6SS-Dependent Lytic Efficiency of Lactobacillus acidophilus

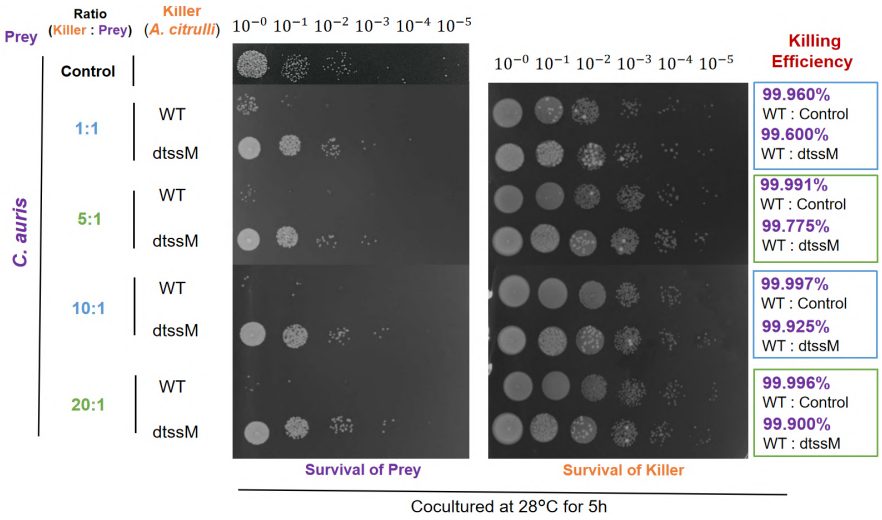


Figure 24: T6SS-Dependent Lytic Efficiency of Lactobacillus acidophilus

Assessed the lytic efficiency of Lactobacillus acidophilus wild-type (AC) and its T6SS secretion system-deficient mutant (dtssM) against Candida auris.

After co-culturing wild-type AC and T6SS-deficient AC (dtssM) with Candida auris, the remaining Candida auris population ratio reached 99.6%. This indicates that AC's T6SS is the primary mechanism responsible for killing Candida auris.

This result directly demonstrates that the killing activity of Acinetobacter citrophila is highly dependent on its T6SS secretion system.

Amphotericin B Hydrochloride Efficacy Testing

Experimental Content: Testing the efficacy of amphotericin B hydrochloride at different concentrations (0 μg/ml, 1 μg/ml, 10 μg/ml, 100 μg/ml) against Candida auris.

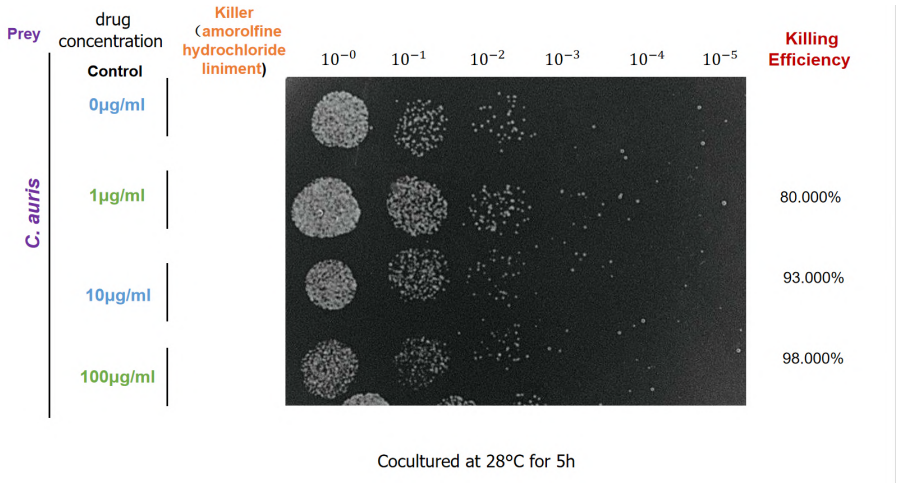


Figure 25: Amphotericin B Hydrochloride Efficacy

Key Findings:

1. Minimum Bactericidal Concentration (MBC) Reference: For Candida albicans and Candida glabrata, the typical MBC range for amphotericin B hydrochloride is 0.125–16 μg/ml.
2. The killing effect of amphotericin B hydrochloride exhibits concentration dependence. At 1 μg/ml (within its MBC range), the killing efficiency was 80.000%.
3. As the concentration increases to 10 μg/ml and 100 μg/ml, the killing efficiency rises to 93.000% and 98.000%, respectively.
4. Despite its significant efficacy at high concentrations, its maximum killing efficiency remains lower than that of wild-type Aspergillus flavus.

Ketoconazole Antifungal Efficacy Test

Experimental Content: Evaluation of ketoconazole efficacy against Candida auris at concentrations of 0 μg/ml, 0.003 μg/ml, 0.03 μg/ml, and 0.3 μg/ml.

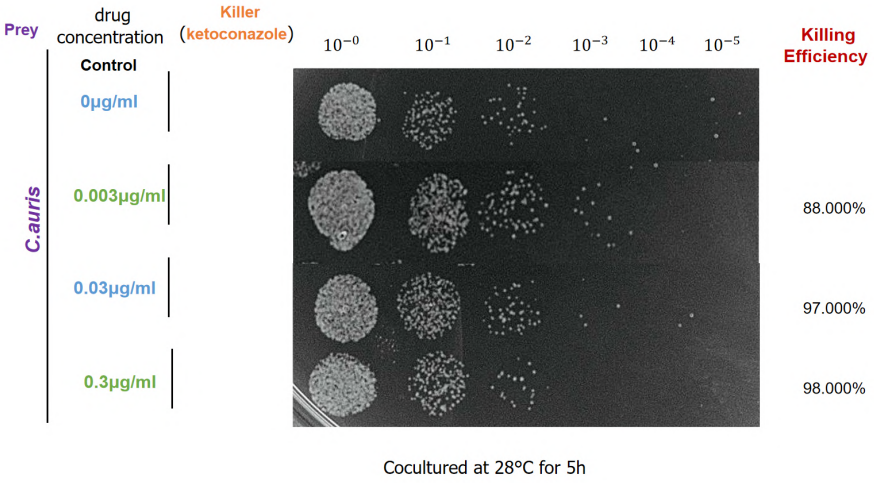


Figure 26: Ketoconazole Antifungal Efficacy

Key Findings:

1. Pharmacological Background: Ketoconazole is a chemically synthesized pyrrole antifungal agent with broad-spectrum activity. Its minimum inhibitory concentration (MIC) against certain Malassezia species can be as low as 0.03 μg/ml, acting by directly damaging fungal cell membranes.
2. Ketoconazole's killing effect is also concentration-dependent. At 0.003 μg/ml, it demonstrated 88.000% killing efficiency.
3. When concentrations increased to 0.03 μg/ml (approximately its MIC value) and 0.3 μg/ml (10× MIC), killing efficiencies reached 97.000% and 98.000%, respectively.

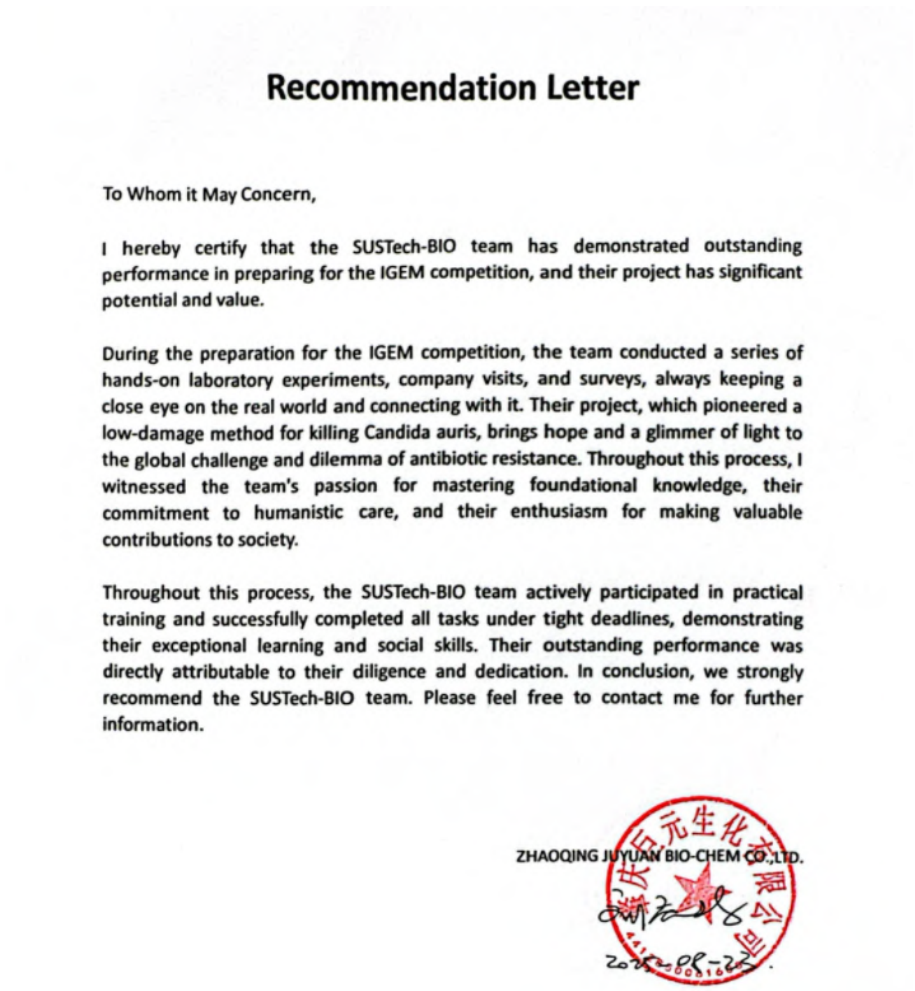
Comprehensive Conclusions

- **Mechanism Determination:** The exceptional killing efficiency (>99.9%) of Citrobacter watermelonis against Candida auris is primarily attributed to its T6SS secretion system, whose efficacy far surpasses traditional antifungal drugs.
- **Drug Efficiency Limitations:** Even at concentrations reaching or exceeding their minimum effective concentrations (MBC/MIC), amorolfine hydrochloride and ketoconazole exhibited a maximum killing efficiency of 98%, indicating an inherent limitation in achieving complete fungal eradication.
- **Application Potential:** Aspergillus citreus demonstrates significant potential as a highly effective biocontrol agent, offering a novel approach to address potential resistance or efficacy limitations associated with existing pharmaceutical treatments.

8.2.2 Preliminary Cooperation Intentions

Based on the above results, we secured two preliminary technical development agreements, one from BGI and the other from Juyuan Biochemical. The version we signed is in Chinese. The following documents are, in order, the English versions of the agreements and the two actual signed documents.

Based on the above results, we have secured one letter of recommendation and two preliminary technical development agreements. The letter of recommendation is as follows:



Recommendation Letter

To Whom it May Concern,

I hereby certify that the SUSTech-BIO team has demonstrated outstanding performance in preparing for the IGEM competition, and their project has significant potential and value.

During the preparation for the IGEM competition, the team conducted a series of hands-on laboratory experiments, company visits, and surveys, always keeping a close eye on the real world and connecting with it. Their project, which pioneered a low-damage method for killing Candida auris, brings hope and a glimmer of light to the global challenge and dilemma of antibiotic resistance. Throughout this process, I witnessed the team's passion for mastering foundational knowledge, their commitment to humanistic care, and their enthusiasm for making valuable contributions to society.

Throughout this process, the SUSTech-BIO team actively participated in practical training and successfully completed all tasks under tight deadlines, demonstrating their exceptional learning and social skills. Their outstanding performance was directly attributable to their diligence and dedication. In conclusion, we strongly recommend the SUSTech-BIO team. Please feel free to contact me for further information.

ZHAOQING JUYUAN BIO-CHEM CO.,LTD.

Figure 27: The letter of recommendation

The technical development agreements are as follows: The version we signed is the Chinese version. The documents below are, in order, the English version of the agreement and the actual signed documents. Meanwhile, BGI's cooperation agreement was based on a verbal commitment from BGI's responsible personnel (with a recorded audio file preserved), signed on their

behalf by an intern.

Letter of intent for cooperation:https://static.igem.wiki/teams/5873/documents/entrepreneurship/letter-of-intent-for-cooperation.pdf

9 Financial Planning

9.1 Cost Assumptions

To ensure the effective implementation of the company's business plan, corresponding financial planning must be established. This process requires reasonable assumptions about future cost structures. Through in-depth discussions with Ms. Yang from a research-based enterprise in South China, we identified key cost elements that may be involved and formulated the following fixed cost structure based on these: Fixed costs include human resource expenditures, training expenses, third-party services, infrastructure operating costs, and marketing expenses. Additionally, legal expenses for protecting T6SS intellectual property, costs for drafting T6SS licensing agreements, and R&D expenditures for developing T6SS are also classified as fixed costs (as Sustech-Bio is not a manufacturing entity, direct variable costs are not accounted for).

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- **Human Resources:** The Sustech-Bio team currently comprises 24 members, with approximately 12 members willing to join full-time following discussions. Over the next five years, each member will be assigned a corresponding job title based on their current team role, such as CEO, CSO, CFO, CDO, CMO, etc. Salaries for all positions will remain unchanged for the first five years. First-year compensation is benchmarked against the average doctoral salary.

According to the Shenzhen Graduate Compensation Survey Report, the average doctoral salary in 2024 is ¥18,500/month (pre-tax, including subsidies). Actual employer labor costs exceed employees' pre-tax salaries due to additional payments for holiday allowances, employee insurance, and medical insurance. Per the Dalian Municipal Human Resources and Social Security Bureau's 2023 Enterprise Labor Cost Information, employers' actual labor costs are approximately 1.36 times the employee's pre-tax salary (i.e., additional expenditures account for 36 % of pre-tax salary). According to CIIC Consulting's 2025 Compensation White Paper, the average salary adjustment rate in the biopharmaceutical industry is 7.5 %.

Year	Pre - tax Monthly Salary of Employees (Yuan)	Monthly Cost for Employers (Yuan)	Annual Cost per Person for Employers (10,000 Yuan)
Year1(2025)	18500	25160	30.19
Year2(2026)	19888	27047	32.46
Year3(2027)	21379	29075	34.89
Year4(2028)	22983	31257	37.51
Year5(2029)	24707	33601	40.32

Figure 28: Cost for Employee

Year	Total Annual Human Resource Cost (10,000 yuan)	Year - on - Year Growth Rate	Cumulative Cost for Five Years (10,000 yuan)
Year1(2025)	362.3	/	362.3
Year2(2026)	389.52	7.5%(+)	751.82
Year3(2027)	418.68	7.5%(+)	1170.5
Year4(2028)	450.12	7.5%(+)	1620.62
Year5(2029)	483.84	7.5%(+)	2104.46

Figure 29: Human Resource

- **Training Costs:** According to Zhaopin's 2024 Talent Development Report for Biopharmaceutical Enterprises, the industry average training cost is ¥6,300 per year. However, for high-end technical positions, investment increases. For instance, BGI's per-capita training cost is ¥8,500 per year, while WuXi AppTec's training cost is ¥11,200 per year. Our team estimates ¥8,000 per year, resulting in an annual training cost of ¥96,000 for the company.
- **Third-Party Services:** Proposed outsourced services include: legal and regulatory fees, clinical research expenditures, preclinical trial costs, clinical trial expenses, consulting fees, and accounting fees.
  - **Legal and Regulatory Fees:** Numerous regulations and licensing requirements exist for R&D, clinical trials, and market promotion. Due to the team's lack of relevant legal and compliance expertise, legal and regulatory services will be outsourced to third parties. The Beijing Municipal Bureau of Justice's "Legal Services Fee Guidelines" (2024 Edition) sets a minimum consulting fee of ¥1,200/hour. For reference, WuXi AppTec's 2024 ATMP compliance service bid price is ¥1,380/hour. We adopt a consulting fee of ¥1,300/hour. With an estimated 40 consulting hours annually, the total annual cost amounts to ¥52,000.
  - **Preclinical Trial Costs:** Based on the NMPA's "Guidance on Costing for Non-clinical Studies of Drugs," the total cost breakdown is as follows. Applying a conservative approach, costs are calculated at ¥71,000,000 over a 24-month period, resulting in an annual average cost of ¥35,500,000.

Trial Type	Cost Range (Renminbi)	Cycle	Main Cost Components
GLP Toxicology Test	8-15 million	6-9 months	Rodent/Non-rodent animal models, pathological detection, biochemical analysis
In vivo Pharmacodynamic Study	6-12 million	6-12 months	Disease model construction (e.g., transgenic mice), pharmacodynamic index monitoring
Pharmacokinetics (PK/PD)	4-9 million	3-6 months	Mass spectrometry detection, tissue distribution analysis
Gene Therapy Safety Evaluation	18-35 million	12-18 months	Biodistribution, vector shedding, reproductive toxicity
Total (Full Preclinical Stage)	36-71 million	18-24 months	Excluding candidate drug preparation costs

Figure 30: Preclinical Trial Costs

- **Clinical Trial Costs:** For Phase I + Phase IIa clinical trials of conventional drugs conducted domestically in China, under a conservative scenario, the costs and timelines directly budgeted are as follows. According to page 128 of the China Pharmaceutical R&D Blue Book (2023) (published by the China Pharmaceutical Enterprises Management Association), the median cost for Phase I clinical trials is RMB 22,000,000, with a typical range of RMB 15,000,000–30,000,000. For conservatism, we adopt the upper limit of RMB 30,000,000. Phase IIa (proof-of-concept) costs reference Tigermed's 2022 China Clinical Trial Cost Insight Report and the CDE's Annual Report on Clinical Trials for New Drug Registration in China (2022): Overall domestic Phase II costs range from RMB 50,000,000 to 100,000,000 (sample size 50–200 subjects), with Phase IIa typically accounting for 60 %–75 % of total Phase II costs. This ratio is supported by publicly available case studies in Appendix B of WuXi AppTec's Cell and Gene Therapy R&D White Paper. Conservatively calculating 70 % of the Phase II upper limit of RMB 100,000,000, the Phase IIa budget is RMB 70,000,000. Therefore, the combined direct investment for Phase I + Phase IIa totals RMB 30,000,000 + 70,000,000 = RMB 100,000,000. Considering R&D failure risks, PharmMole's 2023 China New Drug R&D Success Rate Report indicates that the overall success rate for domestic innovative drugs progressing from Phase I to market launch between 2013–2022 was only 9.7 % (based on 1283 pipeline samples). This necessitates risk-adjusted budgeting: RMB $100{,}000{,}000 \div 9.7 \approx$ RMB 1.03×10^9. Thus, the risk-adjusted capital requirement is approximately RMB 1.03×10^9. Regarding timelines: The NMPA's Statistics on Average Clinical Trial Duration in China (2021–2023) indicates Phase I trials for conventional drugs take 6–15 months (median 10 months). A conservative estimate of 12 months (1 year) is adopted. Mininet's 2022 China Clinical Trial Efficiency Report indicates an average Phase IIa duration of 14.3 months, estimated at 15 months (1.25 years). Quarterly amortization: Phase I RMB 30,000,000 spread over 4 quarters, approx. RMB 7.5×10^6 per quarter; Phase IIa RMB 70,000,000 spread over 5 quarters, approx. RMB 1.4×10^7 per quarter.
- **Consulting Fees:** Zhaopin's 2025 Pharmaceutical Consulting Industry Compensation Report indicates rates of ¥1,200–1,800/hour. McKinsey China Life Sciences Team's ATMP project quotation of ¥1,650/hour provides cross-validation. We anticipate 40 consulting hours annually, projecting annual expenditures of ¥48,000–72,000. The midpoint

of ¥60,000 is adopted.

– **Accounting Fees:** We plan to utilize Kingdee's financial outsourcing service package tailored for biotech startups, priced at ¥18,000 per year.

Stage	Year	Human Cost	Training Expense	Third-party Service	Infrastructure and Operations	Marketing Expenses	Annual Cost Total
Preclinical	2026	362.30	9.60	3555.2	83.3	0	4010.4
Preclinical	2027	389.52	9.60	3555.2	83.3	0	4037.62
Phase I	2028	418.68	9.60	3060	83.3	50	3621.58
Phase IIa	2029	450.12	9.60	5060	83.3	50	5653.02
Phase IIa	2030	483.84	9.60	1400	83.3	50	2026.74

Figure 31: cost summary

9.3 Financing Plan

To ensure adequate financial backing, we believe equity financing is the most suitable approach for three primary reasons: First, we lack sufficient collateral and credit ratings to secure substantial loans. Second, with no projected revenue stream over the next five years, we already face liquidity challenges. Relying on debt financing would impose additional interest payments, further exacerbating this pressure. Finally, by pursuing equity financing rather than debt financing, we can attract venture investors with extensive entrepreneurial experience and broad industry networks, accelerating the company's growth. We plan to secure initial funding of 1 million yuan through research grants in the first year, followed by a more systematic financing strategy starting from the second year.

9.3.1 Financing Benchmarking

The current funding rounds for all innovative drug companies in China are summarized as follows:

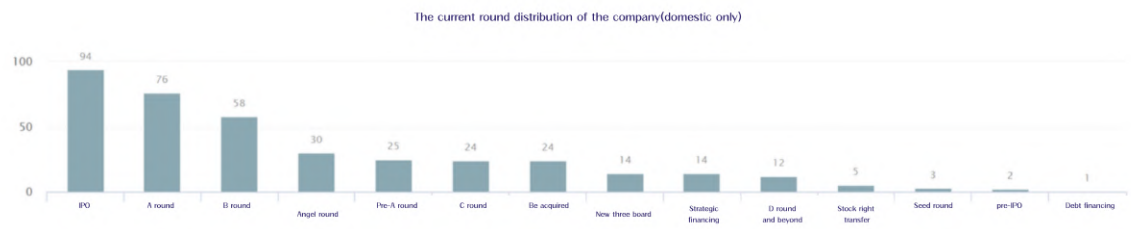

Figure 32: financing benchmarking

Based on information from public data platforms, we conducted a systematic review of angel, Pre-A, and Series A funding cases in China's innovative drug sector over the past two years. Be-

low are detailed records of all relevant funding cases: https://static.igem.wiki/teams/5873/documents/entrepreneurship/innovative-drug-financing-case-studies.pdf

9.3.2 Financing Plan Details

We currently plan three rounds of financing with the following target amounts:

1. Angel Round: RMB 80 million, to be raised during the preclinical phase
2. Pre-Series A Round: RMB 50 million, to be raised prior to Phase I clinical trials
3. Series A Round: RMB 80 million, to be raised prior to Phase II clinical trials

The fund allocation ratio is designed to optimize resource distribution across key areas.

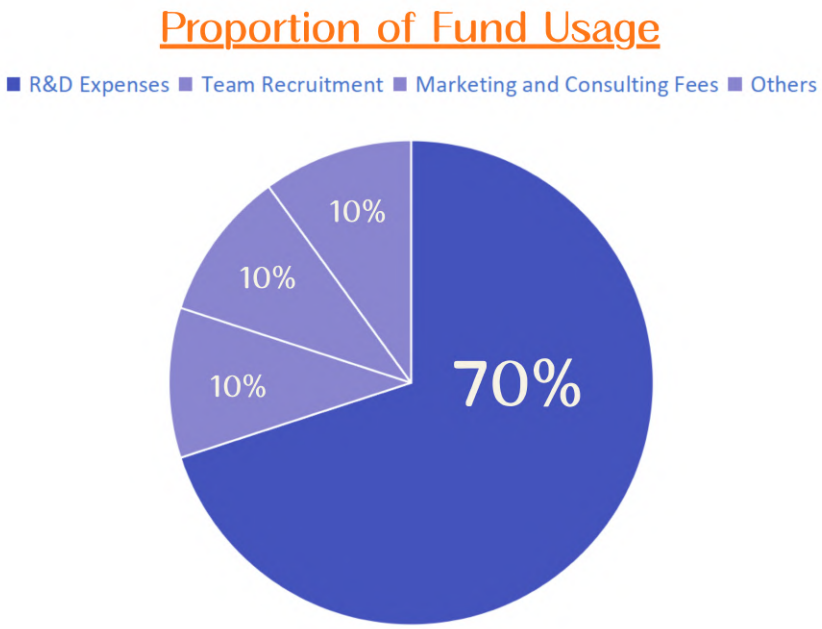

Figure 33: Enter Caption

9.3.3 Enterprise Valuation

We held in-depth consultations with Director Guo from BGI's Investment and Financing Department. When discussing corporate valuation, Director Guo specifically noted that for innovative drug companies, particularly in the very early stages (e.g., when no clinical trials have been conducted and comparable products are lacking), traditional valuation metrics such as market

penetration rates often exhibit significant distortions. Consequently, common valuation methods like the Discounted Cash Flow (DCF) approach and Real Options pricing face substantial limitations in practical application under such circumstances. Minister Guo emphasized that in practice, the valuation of early-stage companies and the amount of funding raised are typically determined through thorough negotiation and consultation with venture capital institutions, rather than relying solely on fixed valuation models or methods. This valuation process places greater emphasis on the actual market environment, the company's potential, and investors' expectations for future development.

9.3.4 Intended Financing Capital

Through the Lingxi Data Platform, we obtained all capital entities that have invested in China's pharmaceutical and healthcare sector over the past two years, ranking them by investment frequency from highest to lowest. Investors with two or more investment instances demonstrate heightened recent interest in this industry and stronger investment intent. Consequently, the likelihood of securing financing through collaboration with these investors significantly increases. During our discussions with Minister Guo, he also generously provided us with a comprehensive list of all capital entities participating in investments within China's healthcare sector. This list encompasses investment institutions across multiple sectors, providing invaluable reference material to better understand active investors within the industry. Through this information, we can conduct in-depth analysis of potential financing channels, evaluate different capital partners' investment preferences and strategic priorities, and formulate more precise strategies for subsequent fundraising efforts. The provision of this resource undoubtedly offers substantial support for advancing our business plan and financing proposals. https://static.igem.wiki/teams/5873/documents/entrepreneurship/financing-frequency-analysis-table-1.pdf

9.4 Cash Flow Situation

Based on the aforementioned financial analysis, we conducted an annual cash flow analysis.

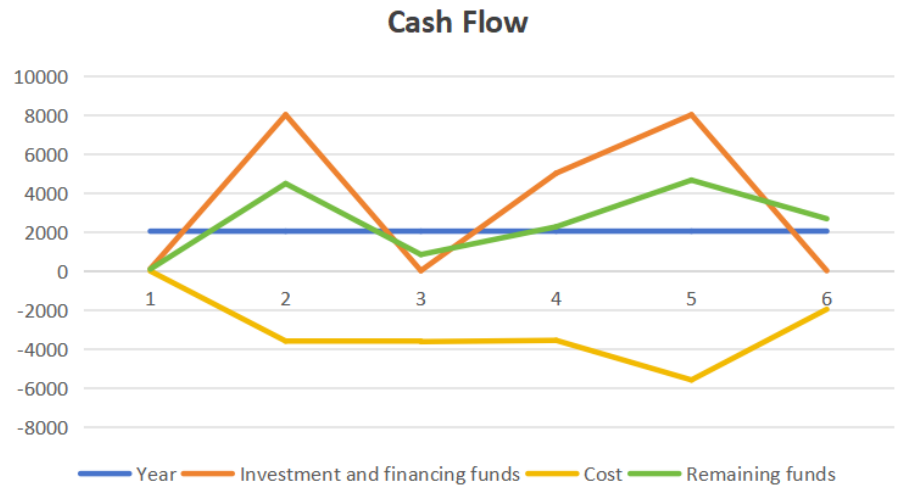

Figure 34: cash flow$_{n}ormalcase$

Based on the above calculations, as shown in the figure, an annual funding surplus can be ensured provided each funding round reaches its projected target. Even during the third RD year—when funding is most constrained—a surplus of 8 million yuan can still be maintained. However, if each funding round only secures 80% of its projected target, as illustrated in the figure, the third, fourth, and sixth RD years will face the risk of a funding chain disruption.

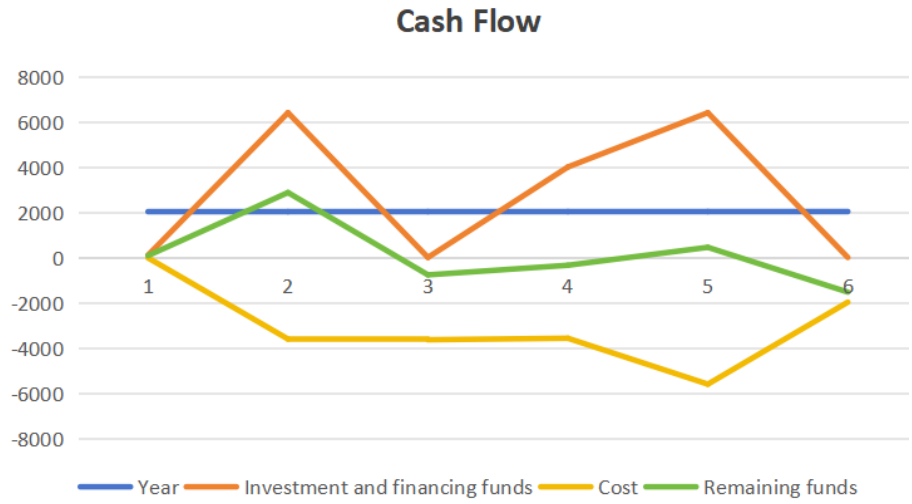

Figure 35: cash flow$_{s}pecialcase$

To this end, we consulted Mr. Wang Haikun of Haikun Capital, who advised that when fundraising falls short of expectations, companies should secure bank loans at the beginning of the year while simultaneously pursuing an additional round of financing to ensure the stability of their cash flow.

10 Risk Control

10.1 Risk Identification and Assessment

To identify key risks, the business model will prioritize **evaluating potential hazards**. Specifically, each risk will be assessed across three dimensions—impact, probability, and uncontrollability—using a **five-point Likert scale** ranging from 1 (low) to 5 (high). The risk index is calculated by multiplying these three factors, and risks are categorized based on this index. A high risk index indicates a critical risk requiring effective monitoring and management, while a low risk index signifies a risk that only requires monitoring.

	RISK	PROBABILITY	IMPACT	RISK RATING	SOLUTION
PRODUCT RISK	Side Effects (High Risk)	3	5	High	Strengthen quality control; test and optimize with feedback.
	Not Included in Medical Insurance Reimbursement	3	5	High	Communicate with medical insurance departments; develop multi - version commercial paths.
	Short Efficacy	4	4	High	Increase R & D investment and cooperate with institutions.
	Side Effects (Medium Risk)	3	3	Medium	Monitor and adjust based on feedback.
	Competitor Threats	4	3	Medium	Monitor competitors and enhance product differentiation.
FINANCIAL RISK	Cash Flow Break	4	5	High	Plan cash flow; control budget and costs; set up emergency funds.
ETHICAL RISK	Ethical Controversy Caused by Engineering Bacteria Therapy	3	4	High	Manage interest conflicts; introduce third - party evaluation; enhance CSR; set up reporting mechanism.
STRATEGIC RISK	Missing Development Opportunities	4	5	High	Monitor market; increase R & D investment; set up innovation fund.
REGULATORY POLICY RISK	Legislative Changes	2	3	Medium	Monitor policies and conduct compliance reviews.
MANAGEMENT RISK	Brain Drain	2	4	Low	Optimize talent management.
SECURITY RISK	Data Leakage	2	4	Low	Strengthen data security and training.

Figure 36: risk identificatoin and assessment

10.2 Risk Management Measures

Tiered Management System High-risk items are subject to monthly board review with immediate intervention triggered; low-risk items undergo quarterly periodic assessment updates to free up management resources.

Separation of Duties Strategy R&D teams focus on technical breakthroughs, while adminis-

trative teams operate independently, creating bidirectional risk isolation.

Collaborative Risk-Sharing Strategy

- **Collaborative R&D Ecosystem:** Establish strategic partnerships with leading pharmaceutical companies like Novartis to share clinical trial resources and R&D data, reducing product development cycle risks.
- **Compliance Alliance:** Partner with specialized legal institutions to jointly manage cross-border patent strategies (e.g., EPO filings) and FDA compliance reviews, mitigating policy barriers.
- **Policy Advantage Utilization:** Leverage special approval channels to reduce regulatory uncertainty.

Strategic Contingency Planning

- **Flexible Business Model Design:** Develop high/medium/low-tier commercialization pathways to adapt to healthcare pricing negotiations and generic drug competition impacts;
- **Legal Risk Reserve:** Establish a dedicated patent opposition fund for rapid response to patent invalidation lawsuits and other unforeseen challenges.

10.3 Specific Measures for High-Risk Threats

10.3.1 Risk of Missing Development Windows

Market Insight Rapid Feedback Mechanism

- Establish a dedicated market monitoring team to regularly analyze industry trends, technological developments, and competitive landscapes, ensuring timely feedback to decision-makers to enable swift adjustments during market windows.

Accelerated R&D Investment

- Increase R&D expenditure, particularly for core technologies and cutting-edge products, while forging collaborations with universities and research institutions to ensure the company remains at the forefront of technological innovation and product upgrades.

Flexible Capital Allocation Mechanism

- Establish an innovation fund to flexibly adjust capital allocation based on market demand shifts, supporting high-potential projects or rapidly responding to unexpected market opportunities to ensure efficient resource allocation.

10.3.2 Approval Risks

Transparent Approval Process Management

- Establish transparent approval procedures and timelines to enable all departments and stakeholders to clearly understand progress and potential obstacles, allowing for proactive preparation.

Pre-Assessment of Compliance Risks

- Conduct comprehensive compliance reviews during project initiation to evaluate legal and policy risks across approval stages, ensuring project plans align with the latest regulations and minimizing approval risks from policy changes.

Policy Early Warning Mechanism

- Establish a policy monitoring mechanism to regularly track updates to relevant laws and regulations, particularly policy changes affecting government approvals. This enables timely adjustments to project strategies to address policy risks.

Government Relations Maintenance and Communication

- Strengthen communication and collaboration with government departments to proactively understand policy trends and approval requirements. Leverage strong government relations to facilitate the approval process and minimize delays caused by communication gaps.

10.3.3 Product-Specific Risks

Multi-Layered Product Quality Control Mechanism

- Implement a rigorous quality management system with multi-tiered controls spanning raw material procurement, production processes, and final product inspection. This ensures compliance at every stage and minimizes risks stemming from quality issues.

Diversified Product Testing and Trial Mechanism

- Conduct small-scale user trials and market testing prior to official launch to gather authentic market feedback. This identifies potential product flaws or shortcomings, preventing brand damage from product issues during large-scale rollouts.

10.3.4 Cash Flow Risk

Short-Term Borrowing and Cash Flow Management Plan

- During periods of peak short-term funding needs, collaborate with banks or financial institutions to secure short-term loans or bill financing, ensuring stable cash flow and mitigating pressure from seasonal demand fluctuations or unpredictable market shifts.

Flexible Budgeting and Cost Control

- Develop flexible funding budgets that adjust resource allocation based on varying business needs. Minimize unnecessary expenditures by optimizing cost controls to maximize resource utilization for every expense, preventing capital wastage.

Contingency Fund Reserves

- Establish a dedicated contingency fund pool to address sudden capital needs or market volatility. This ensures swift capital mobilization during unexpected shortages, safeguarding normal company operations.

10.3.5 Ethical Risks and Countermeasures

Conflict of Interest Management System

- Implement a clear conflict of interest management system. This ensures employees, management, and board members make decisions free from personal interests that could compromise the company's ethical conduct. Strictly regulate disclosure and handling procedures for conflict of interest situations.

Third-Party Ethical Assessment and Oversight

- Engage independent third-party institutions for ethical assessment and oversight. Conduct regular audits of operational conduct to uphold moral and ethical standards across all business processes, promptly identifying and rectifying potential ethical issues.

Corporate Social Responsibility (CSR) Strategy

- Strengthen the implementation of the corporate social responsibility strategy, focusing on environmental protection, social equity, and labor rights. Promote more ethical conduct in production and operations to avoid ethical controversies or social pressure arising from improper behavior.

Feedback and Reporting Mechanism

- Establish anonymous reporting channels enabling employees and external stakeholders to report unethical conduct. Ensure an effective internal oversight mechanism exists to swiftly address ethical violations, preventing their spread or escalation.

11 The iGBA Industry

11.1 Forum Background and Positioning

The iGEM Greater Bay Area Industry-Academia-Research Forum (iGBA) was jointly initiated by University of Macau, Beijing Normal University (Zhuhai), Hong Kong University of Science and Technology, Southern University of Science and Technology, Macau University of Science and Technology, The University of Hong Kong and the Hong Kong University of Science and Technology (Guangzhou). It aims to promote industry-academia collaboration in the Guangdong-Hong Kong-Macao Greater Bay Area (GBA), which is home to both a high concentration of iGEM teams and an emerging biotechnology ecosystem.

iGBA is not only a platform for competition exchange but also a vital bridge promoting the transition of synthetic biology from the laboratory to industrialization. Through multi-dimensional activities such as team exchanges, company visits, expert sharing, and project presentations, iGBA is dedicated to fostering the deep integration of cutting-edge research with industry needs, assisting young innovation teams in achieving breakthroughs in technology transfer, business model construction, and market expansion.

11.2 Value of Project Participation in iGBA

Our project team participated deeply in the 3rd iGBA Forum, gaining the following key resources and insights:

- **Industrial Chain Resource Connection:** Despite the challenges of engaging industry as a student team, we successfully established communication channels with biotech companies. During this year's forum, we successively visited the Shenzhen Guangming Engineering Biotechnology Industry Innovation Center, the Shenzhen Institute of Advanced Technology of the Chinese Academy of Sciences (and its Synthetic Biology Mega-Facility), and the Guangming Yinxing Synthetic Biology Industrial Park.

- **Guidance from Industry Mentors:** During the team-enterprise exchange sessions, representatives from companies such as Bayland Biotech, Yanyin Technology, and Hongxun

Bio provided valuable advice on the project's commercialization path, intellectual property strategy, and pre-clinical research design, particularly offering practical advice on "special drug evaluation pathways" and the application of real-world data.

- **Insights into Policy and Capital:** The forum featured invited guests including investors and policy experts in the synthetic biology field, providing the team with cutting-edge information on topics such as special funding applications in the Greater Bay Area, CDMO cooperation, and cross-border compliance.

11.3 iGBA's Role in Accelerating the Commercialization Path

The iGBA platform provided the following three aspects of commercial support for this project:

1. **Accelerated Improvement of Technology Readiness Level (TRL)** Through face-to-face communication with corporate R&D personnel, the team quickly identified potential bottlenecks in the engineered bacterial gel formulation, such as stability and delivery efficiency, and conducted targeted optimizations in subsequent experiments, enhancing the product's industrial feasibility.

2. **Expansion of Partner Network** During the forum, the team established preliminary cooperation intentions with several local biotech companies, laying the foundation for future collaborations in pilot production, pre-clinical CRO services, and channel development.

3. **Enhanced Project Exposure and Financing Opportunities** As a participating project in iGBA, the team presented its technological advantages and market potential to several

investment institutions during the roadshow session, attracting attention from potential investors and creating conditions for subsequent angel-round financing.

11.4 Future Cooperation Prospects

Starting from iGBA, this project will continue to deepen its interaction with the synthetic biology industrial ecosystem of the Guangdong-Hong Kong-Macao Greater Bay Area, planning to further expand cooperation in the following areas:

- Establishing a joint laboratory with the Shenzhen Engineering Biology Industry Innovation Center to share equipment and pilot platforms.
- Participating in applications for the Greater Bay Area's "Synthetic Biology Special Fund" to seek policy and financial support.
- Connecting with international iGEM teams through the iGBA network to explore opportunities for cross-border technology transfer and joint development.

iGBA is not only an important extension of the iGEM competition but also a key catalyst for synthetic biology innovation projects transitioning from "laboratory concept" to "marketable product." This project will fully utilize the resources of this platform to accelerate technology transfer and commercial landing.


深圳合成生物研究重大科技基础设施
SHENZHEN SYNTHETIC BIOLOGY INFRASTRUCTURE
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SZU-China 2025


合生万物 成就未来


SynBio Challenges


人才是第一资源，创新是第一动力
创新生态