1. Problem Statement

Antimicrobial resistance (AMR) is an escalating global health crisis. It was associated with approximately 4.95 million deaths in 2019 and is projected to cause 10 million deaths annually by 2050 – more than the current mortality of cancer (Antimicrobial Resistance Collaborators, 2022; O'Neil, 2016). In 2019 the Lancet labelled it a "silent pandemic"; reported to be the third leading cause of death after cardiovascular diseases (Murray et al., 2022). The crisis is fueled by the misuse and overuse of antibiotics, as well as bacteria's natural ability to evolve and adapt under drug pressure - rendering many conventional treatments increasingly ineffective (Ventola, 2015).

Bacteriophage (phage) therapy, a century-old method that uses viruses to selectively destroy harmful bacteria, has emerged as a promising alternative. Compassionate-use cases have demonstrated its potential, including a landmark recovery involving a multidrug-resistant infection (Pirnay et al., 2024; Strathdee et al., 2023). This promise stems from phages' exquisite specificity - each phage typically targets only a narrow range of bacterial strains - which enables precise treatment with minimal impact on the surrounding microbiome. However, despite its potential, widespread adoption is limited by a slow and labor-intensive phage matching process - which typically involves isolating the patient's bacterial strain (bacterial isolate), screening it against a library of candidate phages, and validating efficacy through laboratory assays - and the complexity of phage-bacteria interactions (Würstle et al., 2024). The time from request to administration can take a median of 171 days - nearly six months, preventing critically ill patients from access (Aslam et al., 2020). At the Queen Astrid Military Hospital (QAMH) in Belgium, of 1,066 phage therapy requests submitted between 2008 and 2022, only 100 resulted in treatment - a fulfillment rate of ≈9.4% (Pirnay et al., 2024). A detailed analysis of a subset of 260 requests found that the most common reason for rejection was the absence of available phages for the target bacterial species (47.7%) (Pirnay et al., 2024).

If current systems struggle to serve even a few thousand cases, the challenge of scaling to meet the needs of millions of patients at risk from AMR becomes a critical bottleneck. Addressing this issue is essential to realizing phage therapy's full clinical and commercial potential.

To address this challenge, Mystiphage is applying predictive and generative artificial intelligence (AI) tools to rapidly match phages with bacterial targets, and generate new receptor-binding proteins (RBPs) that allow a phage to bind to specific bacteria that cause these infections. The approach uses predictive bioinformatics for initial phage matching, and generative protein models to create new RBP to allow the closest matching phages to bind to novel bacterial isolates. This iterative pipeline reduces the time needed for personalized therapeutic design to hours. To support scalable deployment, Mystiphage is also actively building a *generative RBP bank*—a library of validated RBP designs that can be recombined or adapted for future clinical needs. As AMR continues to rise and infectious threats evolve, merging computational precision with phage biology presents a powerful new strategy for delivering timely and effective treatment.

2. Customer Segments

Mystiphage will operate on a business-to-business (B2B) model, initially targeting clinical phage laboratories and research hospitals engaged in the development of AMR therapeutics and phage-based treatments. While the company is focused on institutional customers, insights from the consumer healthcare space (B2C) will be monitored to guide future product development and long-term market alignment.

Customer Prioritization

Mystiphage has classified its target customers into three strategic tiers based on urgency, regulatory accessibility, and growth potential. The short-term focus (Years 1–5) will be on specialized clinical users operating under compassionate-use frameworks. As regulatory environments mature and phage therapy becomes more mainstream, Mystiphage will expand into larger commercial segments.

Tier 1 – High Priority (Years 1 to 5)

Potential Partners and Prospects Identified:

- Davidson Lab and Maxwell Lab (Canada) – Potential partners in platform development
- UC San Diego IPATH (USA) – Leading clinical phage therapy center
- Phage Canada - Canadian network advancing phage research and clinical translation
- UHN/Sinai Health/other affiliated hospitals of University of Toronto (Canada) – Potential clinical trial and patient access partners
- University of Toronto Temerty Faculty of Medicine (Canada) – Potential collaborator for clinical validation and translational science
- Eliava Institute (Georgia) – Established phage therapy innovator
- Queen Astrid Military Hospital (Belgium) – Advanced compassionate-use program
- Phage Australia – National initiative in cystic fibrosis and AMR management

Emerging Biotech Startups in Phage Therapy
Many early-stage phage companies lack internal capabilities in AI, protein design, or host-range engineering. Mystiphage offers modular, pre-validated RBP solutions to support rapid therapeutic development and host-target expansion.

Key Collaboration Targets:

- BiomX – Developer of the BOLT discovery platform
- SNIPR Biome – Pioneering CRISPR-enhanced phage therapeutics
- Phiogen – Focused on AI-guided directed evolution for phage optimization

Tier 2 – Mid-Priority (Years 3 to 6)

Hospital-Based Phage Therapy Centers
Academic and translational medicine centers with in-house phage therapy capabilities stand to benefit from Mystiphage's computational and wet-lab tools, which streamline formulation for patient-specific pathogens.

Contract Development and Manufacturing Organizations (CDMOs)
CDMOs specializing in biologics and live biotherapeutic products (LBPs) can integrate Mystiphage's RBP modules into their GMP-compliant development pipelines to enhance phage formulation and scalability.

Tier 3 – Long-Term Prospects (Years 5 and Beyond)

Large Pharmaceutical Companies
As regulatory frameworks evolve to support broader phage adoption, Mystiphage will be positioned to provide validated, scalable RBP modules for integration into pharmaceutical R&D programs.

Diagnostics Companies
Companies such as LabCorp and Eligo Bioscience may utilize engineered RBPs as biosensors within next-generation diagnostics for bacterial strain identification.

Agricultural and Food Biotech Firms
Firms such as Intralytix and Phagelux, which deploy phage-based interventions in food safety and agriculture, represent future opportunities for platform diversification.

Strategic Collaboration Opportunities

Mystiphage recognizes that several companies in the phage therapeutics space may serve as both competitors and potential customers. By providing modular RBP design capabilities, Mystiphage can augment their platforms and expand their host-targeting range. The following table outlines collaboration opportunities:

Company	**Strategic Focus**	**Lead Indication(s)**	**Collaboration Opportunity**
Locus Biosciences	CRISPR-enhanced phages	UTIs, *E. coli*	RBP modules to improve specificity and reduce off-target activity
Armata Pharmaceuticals	Multi-phage cocktails	CF, *P. aeruginosa*, *S. aureus*	Support cocktail optimization and regulatory design
BiomX	Natural and engineered phages	CF, DFO	Accelerate phage selection via AI-driven RBP matching
Adaptive Phage Therapeutics	Personalized phage therapies	MDR infections	Expand PhageBank coverage for rare or emerging strains
Intralytix	Clinical and food phage applications	*Shigella*, foodborne pathogens	Enhance host-range for broader use cases
SNIPR Biome	CRISPR-phage therapeutics	*E. coli*, microbiome balancing	Improve targeting to preserve beneficial microbiota

Market Entry Strategy

Given the current regulatory constraints surrounding phage therapy, Mystiphage will prioritize markets with established compassionate-use frameworks that enable physician-initiated treatment. These include the United States, United Kingdom, France, Belgium, Australia, India, and China countries where regulatory pathways allow for earlier deployment and clinical integration (*JCI, 2023; Springer, 2022*). In these regions, Mystiphage will serve as a key partner by supplying AI-designed, wet-lab validated RBPs supported by jurisdiction-specific documentation (*Frontiers, 2025*).

Psychographics

Who is Affected?

Target Consumer Demographics (Patients affected by Antibiotic Resistance):

Age: While antibiotic resistance affects all age groups, research indicates that older adults – particularly those aged 65 and above – are at heightened risk due to greater cumulative antibiotic exposure, increased comorbidities, and more frequent interactions with healthcare settings (*CDC, 2025*; *Oxford University, 2024*).

Health Status: Individuals who have experienced recurrent bacterial infections or have been diagnosed with antibiotic-resistant infections, as well as those with chronic conditions where conventional antibiotic treatments have failed (*CDC, 2025*; *Our World in Data, 2025*).

Geography: Urban and suburban patients in developed markets where access to cutting-edge healthcare is prevalent, though the solution is scalable for global impact (*McKinsey, 2025*).

Economic Profile: Middle to upper-income consumers willing to invest in premium, innovative treatments that promise improved outcomes over traditional therapies (*Healthline Media, 2024*).

Psychographics and Behaviors

- **Risk-Averse for Conventional Failures:** Having potentially experienced the limitations of antibiotics firsthand, these consumers are motivated by their desire

for safe, validated alternatives that come with a strong data-backed promise of efficacy.

Validated Demand for Mystiphage Across Sectors

Mystiphage has received enthusiastic support from key leaders in healthcare, biotech, and academic research, underscoring its critical relevance and urgency. Clinicians emphasized Mystiphage's role in improving infectious disease management, streamlining diagnostic workflows, and addressing life-threatening delays in personalized phage treatment. Experts in AMR and health policy highlighted its potential to strengthen stewardship programs and align with economic frameworks. Following customer conversations with leading phage research centers including the Eliava Institute, Queen Astrid Phage Center, Westmead Institute, IPATH, and Laurent Debarbieux's lab, Mystiphage received strong validation across both commercial and research spheres. They highlighted significant interest in our AI-driven scalability and the therapeutic potential of phage applications for AMR. Simultaneously, academic researchers emphasized the value of Mystiphage's focus on clinical datasets, biological innovation, and openness to collaboration, reinforcing widespread confidence in our ability to bridge the gap from lab to clinic to market.

Purchasing Habits

Willingness to Invest in Health: Given the serious implications of antibiotic resistance (with the CDC reporting over 2.8 million antibiotic-resistant infections and more than 35,000 deaths annually in the U.S.) (*CDC, 2025*), these individuals are prepared to invest in treatments that may initially come at a premium if it means improved health outcomes (*Healthline Media, 2023*).

Global Phage Therapy Market

Mystiphage is strategically positioned in the fast-growing CAD $160M global phage therapy market, targeting a $50M serviceable segment focused on customizable, personalized therapeutics (Business Research Insights, 2025). With plans to capture $8M–$10M over the next 3–5 years, our growth is supported by a projected 8.4% compound annual expansion (Technavio, 2024). As antibiotic resistance rises and conventional solutions falter, phage therapy rapidly emerges as a mainstream, life-saving alternative (Mordor Intelligence, 2025). The entire sector is now aligning with the booming global AMR industry, unlocking new urgency and market adoption (WHO,

2025). Looking ahead, this trajectory could expand into a $50B TAM, $18.5B SAM, and up to $1.96B SOM, giving Mystiphage a pathway to scale with global impact (Waveup, 2025; Phi Consulting, 2024).

3. Value Proposition

Mystiphage overcomes the core bottlenecks of phage therapy - slow phage matching, limited coverage, and low fulfillment rates - by combining rapid predictive analytics and adaptive protein engineering with a modular, ever-growing therapeutic bank. Working with some of the top phage labs in Canada, we enable:

- Rapid phage matching from our curated phage and RBP bank using receptor-level prediction methods.
- On-demand, AI-guided generation of novel RBPs when no known match exists.
- A modular, reusable therapeutic bank, allowing validated candidates to be deployed more efficiently in future cases.

Mystiphage is making personalized phage therapy **clinically viable at scale** - turning a last-resort option into a frontline defense against one of the deadliest threats of our time.

Current Challenges Surrounding Phage Therapy

Phage therapy remains a promising but complex solution to AMR, facing critical roadblocks in deployment and development (Kortright et al., 2019; Strathdee et al., 2023). One major hurdle is the **lack of centralized phage libraries** – each lab curates its own isolated database, preventing global coordination and rapid matching of phages to infections (McKenna, 2023). To navigate this, experts like Dr. Strathdee (Co-Director at the Center for Innovative Phage Applications and Therapeutics) still rely on **manual outreach**, contacting individual labs – including commercial ones whose access may be gated by stakeholder priorities (Corbyn, 2019). Moreover, **effective lytic phages** are not always discovered or present in these libraries for every pathogen, and screening for the right candidate is often unsuccessful (Knezevic et al., 2021). This problem is compounded when **culturing bacteria** becomes difficult due to antibiotic interference, limiting the ability to assess phage efficacy (Kim et al., 2025).

The process of matching phages to a patient's infection is often slow and fragmented, with coordination sometimes required between multiple laboratories to locate and test candidate phages (Corbyn, 2019; McKenna, 2023). Such delays are particularly problematic in acute infections like sepsis, where rapid intervention is critical - clinical guidelines indicate that every hour of delay in effective antimicrobial therapy can

increase mortality (Kumar et al., 2006). Emerging approaches such as metagenomic DNA sequencing could help bypass traditional culturing, accelerating phage identification and delivery (Dedrick et al., 2019). However, regulatory and ethical barriers persist: in many jurisdictions, the clinical use of genetically modified phages is either prohibited or subject to stringent restrictions, limiting the adoption of advanced engineering solutions (Anomaly, 2020).

Major Challenges in Screening Phage Therapy Candidates

Phage screening suffers from a lack of **standardized protocols**, leading to inconsistent results and difficulty comparing these results across labs (Kline et al., 2025; Onallah et al., 2024). Traditional phage screening still depends on methods that are both resource-intensive and slow, which can constrain its broader application (Bayat et al., 2024). Adding to the complexity is **bacteria evolving phage resistance,** making it hard to predict long-term efficacy or reuse (Abedon, 2025). Complicating this further, **phage-antibiotic interactions** must be carefully monitored, as some antibiotics inhibit bacterial growth to such an extent that phage replication becomes impossible (Pons et al., 2023). Altogether, these bottlenecks reinforce the need for integrated platforms, like Mystiphage, that offer both predictive modeling and validated, actionable results.

Key Benefits

To do this, libraries of protein/sequences are used to train the generative and predictive models:

We enhance existing phage libraries with fine-tuned host ranges, enabling precise targeting of diverse bacterial strains, and reduce trial failure risks for pharma and CDMO partners through predictable efficacy and optimized binder selection. Our custom solutions serve both human and animal health, generating validated phage cocktails for clinical use or ongoing research. With GMP-ready RBP modules and unmatched binding specificity, Mystiphage offers broad applicability across therapeutics, diagnostics, and agriculture – seamlessly plugging into biopharma pipelines to accelerate preclinical validation and reinforce global AMR preparedness.

Mystiphage's AI-Driven Phage Matching Pipeline

We begin with a predictive model that selects the most effective RBP from our curated phage/RBP bank based on a patient's bacterial isolate. If the match is strong - based on prior lab data or in silico binding predictions - we proceed with it. If not, we activate our generative pipeline:

1. The selected RBP is encoded into a structural and sequence representation
2. A masked protein language model hallucinates new RBP variants, generating a diverse set of candidates
3. A diffusion-based protein folding model co-folds each RBP with the target bacterial receptor
4. Binding affinity and other metrics are evaluated through structural modeling and/or molecular docking
5. Top-scoring candidates are used to iteratively refine future generations via Markov Chain Monte Carlo methods or reinforcement learning
6. Final designs are experimentally validated in the lab to confirm efficacy

This closed-loop, AI-guided process enables rapid and precise design of custom phages - even when no natural match exists - cutting development time from months to hours and enabling scalable, personalized therapy for drug-resistant infections.

Harnessing Mystiphage AI with MIT's Boltz-2 and ESM for Predictive Protein Design

Mystiphage will also be utilizing MIT's Boltz-2 AI model concurrently with our AI model. Boltz-2 is the supportive engine that drives Mystiphage's ability to intelligently design receptor-binding proteins (RBPs) for next-generation therapeutic phages. Its primary purpose is to evaluate the structural and functional quality of AI-generated protein sequences, allowing us to identify those with the highest potential for effective bacterial targeting. By simulating how these proteins fold and interact, Boltz-2 helps streamline and prioritize candidates for lab validation.

Furthermore, Evolutionary Scale Modeling (ESM) will be Mystiphage's language model. ESM is a protein language model that learns biological structure and function directly from amino acids sequenced using unsupervised deep learning.

Technology Integration with Existing Lab Workflows

Mystiphage's platform is designed to complement, not replace, the technologies already standard in microbiology and clinical laboratories.

1. **Culture Systems & Automation:**
    - Phage-based assays can be run in parallel with traditional bacterial culture and colony counting methods.
    - Integration with automated plate readers and colony counters ensures results can be digitized and compared seamlessly with existing microbial growth data.
2. **Molecular Diagnostics (PCR/qPCR, NGS):**
    - Mystiphage's workflow can directly feed into qPCR and sequencing systems used for pathogen identification and resistance profiling.
    - Digital data outputs can be exported in formats compatible with LIMS (Laboratory Information Management Systems).
3. **Laboratory Information Systems (LIS/LIMS):**
    - Results from Mystiphage assays can be exported in HL7/FHIR-compatible data formats, allowing easy integration into hospital electronic medical records and diagnostic databases.
4. **Biosafety & Lab Equipment:**
    - Since the platform uses bacteriophages (non-pathogenic to humans), no additional biosafety infrastructure is required beyond BSL-2 (already standard in most microbiology labs).
    - Uses standard consumables (agar, media, pipettes, 96-well plates), lowering adoption barriers.
5. **Scalability:**
    - The platform is modular, meaning small labs can adopt benchtop versions while high-throughput labs can use automated robotics for scaling.

What Makes our RBP's Valuable?

1) Mystiphage RBPs will be able to bind to high-priority pathogenic bacterial strains namely: Enterobacterales (carbapenem-resistant, third-generation cephalosporins-resistant), Acinetobacter baumannii (carbapenem-resistant), and Pseudomonas aeruginosa (carbapenem-resistant).
    a) **Carbapenems** are a powerful class of broad-spectrum antibiotics like imipenem and meropenem, typically used for severe infections such as pneumonia, UTIs, and bloodstream infections (*Merck Manual, 2024)*. Their resistance severely limits treatment options and poses a major threat in healthcare settings.
2) Our lab-tested RBPs with proven host range and binding affinity are worth more than in silico predictions.
3) Our RBPs will be compatible and highly modular with phage engineering platforms (e.g. CRISPR workflows), making them more attractive/valuable.

Mystiphage is redefining the phage therapy landscape by slashing development timelines from 6 months to just hours – an urgent leap forward for patients battling life-threatening, antibiotic-resistant infections. Through the fusion of AI-generated RBPs and in-house wet-lab validation, our platform enables fast, personalized antimicrobial solutions that scale clinically and commercially.

4. Barriers of Entry/Differentiation

Part One: Competitive Analysis & Barriers to Entry

Competitive Analysis

Direct Competitors in Product:

Currently, there are several alternative approaches to tackling antibiotic-resistant bacteria and infections beyond antibiotics and phage therapy.

1) **Antimicrobial Peptides (AMPs)**
    a. Naturally occurring molecules that can kill bacteria by disrupting their membranes. However, they often have stability issues and can be costly to produce (Huan et al., 2020).
2) **Immune Modulation Therapies**
    a. This therapy works by boosting the body's immune response to fight infections rather than directly targeting bacteria. These therapies may not work for immunocompromised individuals (Strzelec et al., 2023).
3) **Probiotics and Microbiome Engineering**
    a. This technique involves using beneficial bacteria to outcompete harmful ones. The challenge is ensuring consistent efficacy across different individuals (Yaqub et al., 2025).

Competitor Analysis: AI-Driven Startups in Phage Screening

Mystiphage outpaces competitors by leveraging a dual-layer AI platform – combining generative models with predictive binding simulations – to engineer novel RBPs directly from bacterial genomes. Unlike most phage labs relying solely on predictive tools, we create entirely new protein candidates, dramatically expanding therapeutic possibilities. What truly sets us apart is our in-house dry lab capability, which makes Mystiphage faster, more accurate, and more actionable than any other RBP discovery company in the space.

Feature	Mystiphage	PhageAI	Locus Biosciences	Cradle	Precision Phage
Core Focus	AI-generated RBPs for phage design	Phage genome characterization	CRISPR-enhanced phages	AI-powered protein design for synthetic biology and therapeutic applications	Genome assembly and annotation
AI Model Type	Masked Protein Language Models + Diffusion-Based Predictive Binding Models	NLP-based genome annotation	Machine learning for interaction prediction	Protein language models fine-tunes for functional prediction and design	Browser-based genome pipeline
Input	Bacterial strain genome → AI-generated RBP sequence	Phage genome sequences	Large genomics data sets	Protein sequences, target functions, and design constraints	Raw phage genomic data
Output	Predicted RBP and likelihood of bacterial infection	Phage function, taxonomy, lifestyle	Therapeutic phage cocktail design	Optimized protein sequences with predicted functional properties	Annotated genome data
Validation Step	Wet-lab validation of RBP–strain interaction	No wet lab; in silico only	Preclinical + clinical testing	Wetlab validation via partner labs	Not emphasized

Value Proposition	Fast, precise RBP matching for strain-specific phage therapy	Rapid annotation & discovery	High-throughput CRISPR phage therapies	Accelerates protein engineering with generative AI for novel therapeutics	Streamlined annotation
Customer Target	Pharma, Agri-biotech, Animal Health	Research labs, bioinformatics users	Big Pharma partners	Biotech startups, pharma R&D teams, synthetic biology researchers	Academic & clinical researchers
Differentiator	End-to-end AI pipeline from design to validation	In silico only, no lab validation	Uses CRISPR to kill bacteria	Combines generative protein design with functional prediction in one platform	Focus on genome prep, not prediction

Indirect Competitors (workflows our system improves)

Traditional Phage Screening Methods: Slow, Costly & Reactive

Most legacy phage companies rely on time-consuming wet-lab screening as their starting point, taking weeks to months on average to match phages with patient isolates. Organizations like Adaptive Phage Therapeutics, Intralytix, BioChimPharm, and the Eliava Phage Therapy Centerbuild their therapies through exhaustive lab-based testing, enrichment, and fixed screening cycles. Mystiphage surmounts this bottleneck with a generative AI platform that designs RBPs instantly – dramatically reducing trial-and-error and compressing development timelines to just hours By shifting discovery upstream into the AI layer, we eliminate wasted resources and accelerate therapeutic delivery.

Static Phage Libraries: Inflexible & Lagging Resistance

Several competitors build therapies around curated phage banks – repositories that potentially lose therapeutic potential as bacterial strains evolve. SNIPR Biome's CRISPR-modified phages and Armata's fixed cocktails are promising but limited by predefined library content. Felix Biotechnology and Phiogen attempt RBP selection yet still depend on phage pools that aren't built dynamically. Tools like PHASTER, PHAGELeads, PHANOTATE, PhageAI, and PhagesDB support genome annotation or community matching but lack generative capabilities and adaptability to novel clinical bacterial isolates. They help analyze phage genomes but do not design new ones.

Why Mystiphage Wins: Mystiphage offers a future-proof alternative: our generative models customize RBPs in real time, directly from bacterial genomic inputs. This means our binders are adaptable, precise, and adapt to microbial evolution. We're not stuck in laborious phage matching or static phage banks. We generate bespoke RBPs, validate them in-house, and deliver functional phage cocktails faster, cheaper, and with greater precision, all while being able to adapt to evolving bacterial infections.

Barriers to Entry

Regulatory Pathways:

Mystiphage is uniquely positioned to operate in regions that have embraced personalized phage therapy through **compassionate-use frameworks**. Countries like the **UK, France, Belgium, Australia, India, China**, and the **United States** allow hospitals and research labs to administer phage treatments with minimal regulatory friction – primarily through physician referrals and hospital exemptions. In these settings, we are not required to pursue full drug approval, but instead provide targeted technical documentation (e.g., sequence data, safety profiles, validation results), enabling a streamlined supply of RBPs as investigational tools (*JCI, 2025; Springer, 2021; Oxford Academic, 2023*).

Adoption Insights from Clinical Stakeholders

Mystiphage has received constructive feedback from clinicians, biotech leaders, and academic researchers. Clinicians highlighted the urgency of accelerating phage matching and delivery - especially in resistant infections - but emphasized the need for clear protocols, dosing guidelines, safety data, and decision authority structures before

routine use is feasible. Hospital-level approval mechanisms and cost structures also play a decisive role - especially in systems where phages are not yet standardized or readily stocked.

Country-Specific Documentation Models:

United Kingdom (Moderate) Under oversight from the Medicines and Healthcare products Regulatory Agency (MHRA), Mystiphage can supply **unlicensed biologicals** if a physician assumes responsibility for patient use. Documentation is provided to hospitals rather than national regulatory bodies, allowing agile therapeutic deployment (*EuroGCT, 2024*).

France (Moderate) Through the **hospital exemption pathway**, French institutions can request patient-specific RBPs without commercial approval—though we must comply with EU GMP standards when working directly with hospitals (*Salud por Derecho, 2023*)

Belgium (Streamlined) Belgium's **Queen Astrid model** facilitates personalized phage production under localized approvals. This efficiency supports our rapid-response workflow and fits seamlessly within individual hospital-led treatment plans (*Phage Directory, 2019)*.

Australia (Moderate) Mystiphage can supply RBPs under the **Special Access Scheme**, where hospitals secure case-specific ethics approvals. We prepare supporting data tailored to each patient scenario – enabling flexible engagement with clinicians (*KU Leuven, 2024*)..

India (Light) Though lacking formal regulations, India supports compassionate-use phage therapy through **hospital ethics committees**. With minimal documentation requirements, Mystiphage partners closely with local labs, allowing for low-barrier entry (*India Today, 2025; The Microbiologist, 2023*).

China (Emerging) Phage therapy is categorized as **investigational**, and Mystiphage can operate under **hospital-led approvals**. Regulatory clarity continues to develop, offering room for early market leadership as frameworks evolve (*CreatiPhage, 2023; Frontiers, 2023*).

United States (Structured) Thanks to FDA advancements, we can supply RBPs within a **master IND or defined phage bank** – especially for patients ineligible for trials due to urgency or uniqueness. This enables responsive, ethically driven access without filing separate INDs for each RBP sequence (*FDA, 2021; MDPI, 2025*).

Intellectual-Property Concerns:

Mystiphage faces key intellectual property challenges in securing and defending its innovations. Naturally occurring phages and RBPs are difficult to patent, making it easier for competitors to isolate similar strains and dilute exclusivity. To address this, Mystiphage focuses on **engineered RBPs**, which have stronger IP potential – but must demonstrate clear inventive steps to meet patent standards. Navigating global IP frameworks adds complexity, as the U.S. and EU systems differ substantially, affecting international protection strategies. The landscape is further complicated by **patent thickets** and evergreening tactics, where overlapping claims and entrenched portfolios can obstruct market entry and drive up licensing costs. Mystiphage's IP approach must balance innovation with strategic differentiation to preserve defensibility across jurisdictions.

Part Two: IP Audit, IDF & Prior Art Search

Competitor Intellectual Property Landscape

The competitive landscape in phage therapy is characterized by a diverse array of intellectual property holdings, particularly among firms deploying traditional development pipelines. Competitors frequently secure patents on protocols for phage isolation and screening – methods heavily reliant on laboratory experimentation and empirical characterization. Moreover, proprietary formulations of phage cocktails, defined by specific strain ratios and host-range coverage, are commonly protected. These patents aim to safeguard compositions capable of addressing broad-spectrum bacterial challenges. Additionally, delivery mechanisms, such as controlled-release systems and hybrid therapeutics combining phages with adjunctive agents, are included in competitor portfolios and represent further layers of complexity.

Third-Party IP Exposure:

At present, Mystiphage anticipates only minimal third-party intellectual property licensing, primarily involving non-core elements such as graphical assets (e.g., Canva or Flaticon resources). The core AI infrastructure, including model architecture and

computing workflows, operates independently and is free from restrictive IP constraints.

Prior Art Evaluation and Strategic Differentiation:

An exhaustive review of existing patents and published applications has identified no disclosures pertaining to an integrated system with capabilities comparable to Mystiphage's platform. Specifically, no prior art demonstrates generative RBP design directly from bacterial genomic sequences for the purpose of improving phage infectivity. While certain filings discuss engineered RBP modifications or computational support for phage discovery, they lack the dynamic, real-time generation architecture that underpins our proprietary approach.

Mystiphage's platform is distinguished by its continuous-learning models, which iteratively generate novel RBPs tailored to patient-specific bacterial data – delivering therapeutic candidates with unmatched precision and adaptability. In contrast, competitor IP portfolios largely encompass legacy methodologies and incremental enhancements. Consequently, Mystiphage's design framework and end-to-end generative capabilities remain defensible and unencumbered, offering a substantial competitive advantage in both innovation and regulatory positioning.

Regulations in Regards to Boltz-2 Usage Rights, Commercialization, and Restrictions (MIT Model)

Permitted Uses of Boltz-2

Boltz-2's open-source nature offers considerable flexibility for commercial applications. Users are permitted to integrate Boltz-2 into proprietary software and monetize access through licensing or subscription-based models. The codebase can be modified, retrained on specialized datasets, and extended to serve niche applications – such as RBP co-folding with bacterial receptors. Additionally, Boltz-2 may be redistributed, either freely or as part of a commercial offering to academic institutions, biotech firms, or hospital-based labs. Developers may also deploy Boltz-2 as a Software-as-a-Service (SaaS) platform to provide cloud-based screening capabilities and have the right to sublicense adapted versions under separate commercial agreements.

Licensing Restrictions under MIT

Although Boltz-2 is released under the permissive MIT License, several legal requirements must be upheld. Any derivative work or distribution must retain the original MIT License of text and attribution. Users may not hold the original developers or MIT liable for any damages or misapplications of the model. Finally, while modified versions may be commercialized, developers may not claim exclusive rights over the base model, which remains freely available to the public.

Part 3: SWOT Analysis & Moat Definition

Strengths	**Weakness**	**Opportunities**	**Threats**
AI-Driven Model: Enables rapid and precise RBP generation, eliminating slow traditional screening processes.	**Limited Expertise in AI Model Development:** Early-stage knowledge and refinement required for complex AI-driven phage design.	**Expansion into Multiple Markets:** Application across diverse bacterial infections, enabling broader therapeutic impact.	**Market Resistance to AI-Based Therapy:** Healthcare providers may prefer traditional methods due to familiarity and established protocols.
Collaborations with UofT Labs: We have an interdisciplinary team that combines AI, bioinformatics, and phage biology expertise to innovate at the intersection of computational and biological sciences.	**Regulatory Uncertainty:** Phage therapy is an emerging field with evolving approval standards, which may slow market entry.	**Collaborations with Pharma & Biotech:** Potential partnerships with established firms to accelerate commercial adoption.	**Regulatory Approval Complexity:** Navigating evolving phage therapy regulations could delay commercialization.
Reduced Dependency on Antibiotics: Provides an alternative solution that directly	**Computational Costs:** AI model training requires compute power, potentially increasing	**Government & Research Grants:** Leverage funding opportunities for AI-driven healthcare solutions.	

combat antibiotic resistance.	operational expenses.		
Data-Driven Infectivity Scoring: Uses advanced ML techniques to optimize phage selection based on empirical infectivity data.		**Integration with Diagnostic Tools:** Enhance phage therapy precision by linking AI-generated RBPs with bacterial diagnostics.	
Personalized Phage Therapy: Tailors treatment to individual bacterial genomes, improving efficacy and reducing trial-and-error approaches.		**Provide Solutions for Multiple Diseases:** Extend beyond antibiotic-resistant infections to cover broader microbiome-related conditions.	
Proprietary AI Technology: Advanced machine learning algorithms enable rapid, precise RBP design, reducing discovery timelines and costs compared to traditional methods.		**Platform Diversification:** Extend AI tools to other areas (e.g., antibody design, microbiome modulation) to diversify revenue streams.	
		Public-Private Funding: Grants from organizations like CARB-X and the WHO for AMR innovation could subsidize R&D.	
		Global Expansion: Emerging markets like India and South	

		Africa, with high AMR burdens, offer untapped opportunities.	

5. Go-To-Market Strategy

Mystiphage will initiate its market entry in regions with established compassionate-use frameworks -such as the UK, France, Belgium, Australia, India, China, and the United States -where phage therapy adoption is already supported by streamlined clinical protocols. Year 1 will focus on penetrating academic phage labs and early biotech adopters, leveraging partnerships and documented case validations to build credibility and secure initial clients. By Year 3, expansion into larger pharmaceutical and CDMO networks will be supported by a growing generative RBP-phage cocktail library.

Elements Required for a Future Successful Launch:

- Finalized dual-stack AI platform (generative + predictive)
- Integrated wet-lab validation protocol
- Initial cohort of customizable RBP-phage combinations
- Technical documentation aligned with compassionate-use standards
- Key partnerships with leading phage labs and clinician networks
- Success metrics: number of RBPs delivered, turnaround time (weeks vs. months), patient outcomes, and repeat customer conversion rate

Distribution Strategy:

Mystiphage employs a hybrid B2B distribution model that pairs its AI-generated RBPs with proprietary phages from customer labs to create wet-lab validated, personalized phage cocktails. These therapeutics are encapsulated in oral capsules formulated by Mystiphage for streamlined deployment in compassionate-use clinical settings. Customers initiate requests via secure digital channels, submitting bacterial genomic data that guides RBP design. Physical delivery and validation occur at dedicated wet-lab centers before capsules are shipped directly to hospital or lab partners. This dual-format system—digital input and tangible output—is highly customizable,

cost-efficient, and integrates seamlessly into existing workflows, allowing institutions to leverage next-generation precision antimicrobials with minimal logistical friction.

Integration with Customer Operations

Mystiphage is designed to plug seamlessly into B2B workflows within phage therapy labs and diagnostic centers. Customers submit patient-derived bacterial genomic data; Mystiphage returns AI-generated, lab-validated RBP-phage combinations—complete with technical and regulatory documentation. This system reduces time-to-treatment from months to weeks, aligning with customer priorities around speed, precision, and adaptability. In the longer term, Mystiphage's growing cocktail archive will enable partners to bypass AI deployment in common cases, further enhancing operational efficiency.

Phase	Timeline	Key Activities
Pre-Launch	Q1-Q2 Year 1	Finalize alpha AI pipeline; begin genome curation and benchmarking; initiate wet/dry lab training; set up branding and IP groundwork (trademark and patent drafting)
Foundation Buildout	Q2-Q3 Year 1	Set up wet lab pipeline and biobank access; initiate AI-clinical integration training; start stakeholder interviews; identify early strategic partners; begin risk mapping.
Soft Launch	Q3-Q4 Year 1	MVP outreach and use case prioritization; complete provisional patent filing; begin pilot discussions and customer onboarding; initiate regulatory workflow testing.
Full Launch	Q1-Q2 Year 2	Beta platform launch; secure seed funding; close first customer agreement; expand into clinical validation studies; initiate regulatory filings and clinical partnership development.
Scale-Up	Q3-Q4 Year 2	Scale AI model to multi-host prediction; expand phage/RBP library; onboard pharma and CDMO partners; optimize logistics for phage delivery.
Commercialization	Q1-Q2 Year 3	Commercial rollout in compassionate-use countries; regulatory and clinical partnerships in

		place; begin RBP delivery and platform monetization.

6. Selling and Customer Relationships

Promotion and Advertising Strategy:

Mystiphage's go-to-market strategy is centered on building trust and urgency among early adopters in clinical, biotech, and hospital environments where rapid access to personalized phage solutions is critical.

We will prioritize strategic partnerships with:

- Hospital labs and clinicians treating drug-resistant infections under compassionate-use frameworks
- Biotech R&D teams seeking AI-enabled phage matching or protein engineering support
- Translational researchers looking to scale phage pipeline infrastructure

To engage these audiences:

- We will launch **targeted, value-driven outreach** through direct referrals, clinical networks, and personalized campaigns, highlighting our AI platform's ability to reduce discovery time from 3-4 months to just hours.
- **Co-developed pilot programs** will serve as flagship case studies, offering discounted access in exchange for performance data and testimonial use.
- We will attend flagship industry and clinical conferences and high-profile investor forums (e.g. Phage Futures, ASM Microbe, H.C. Wainwright Annual Global Healthcare Conference) will serve as launchpads for **workshop sessions, poster presentations, invite-only roundtables**, **and KOL engagement**.
- We will activate **endorsement partnerships** with respected Canadian phage labs, which will serve not only as credibility signals but as co-publication and co-validation partners.

All of this will be supported by a lean but high-impact suite of marketing assets, including:

- Short-form explainer videos and visual case studies tailored to biotech buyers
- Modular pitch decks customized for investors, pharma, and hospital settings
- Scientific literature with technical details for the research community
- Landing pages optimized for conversion (demo sign-up, collaboration inquiry, or whitepaper download)

By focusing on narrow, high-ROI channels with direct conversion paths, Mystiphage will activate our early market and position ourselves as the clinically viable, AI-first efficient solution in phage therapeutics.

Selling Process

Mystiphage relies on a consultative, B2B sales process led by our senior officers. Given the complexity and specificity of our offering, trained external sales personnel are not required. Instead, direct engagement will occur through technical consultations and customized pilot proposals with partner institutions. Initial customers will be onboarded through tailored RBP design trials and secure documentation transfer workflows.

We will also capitalize on scientific networks and word-of-mouth referrals, particularly through individuals with direct connections to pharmaceutical company representatives. This organic approach minimizes costs while fostering trust and long-term partnership potential. Supplemental materials such as pitch decks and technical briefs will support all sales efforts by clearly articulating our approach's value, scientific differentiation, and regulatory readiness.

Sales Enablement and Training

To facilitate effective customer acquisition and onboarding, Mystiphage will equip its domain experts - wetlab, drylab, and hardware subdivisions – with structured internal training modules. These professionals will deliver targeted briefings on RBP design protocols, regulatory frameworks across jurisdictions, and integration guides for genomic data submission.

Customer Retention and Referral Strategy

Mystiphage prioritizes sustained customer satisfaction through tailored retention strategies and referral incentives. Each lab partner will be assigned a dedicated liaison to provide quarterly check-ins, ensuring responsiveness to emerging scientific and regulatory needs. Repeat-use discounts and early access to model updates will help maintain client loyalty, while collaborative opportunities – such as contributing to cocktail development – strengthen scientific rapport.

Relationship Management Infrastructure

Mystiphage's customer relationship tools are designed to integrate seamlessly with our B2B infrastructure. We will implement CRM platforms (e.g., HubSpot or Notion CRM) to manage pilot engagements, referrals, and follow-ups. Secure data portals will facilitate bacterial genome uploads and documentation delivery, while Slack workspaces or private forums will support real-time coordination among collaborating labs.

Automated onboarding workflows - complete with instructional email sequences and explainer kits - will further streamline the customer journey and ensure frictionless integration into our clients' therapeutic development pipelines.

7. Business Model/Revenue Streams

Revenue Model Overview:

Mystiphage operates a hybrid revenue model designed to scale efficiently and capture value across the full drug discovery lifecycle. Our model consists of two core streams:

1. **Fixed Fee per Therapeutic Candidate:** Clients pay a base fee ranging from **$5,000 - $8,000** per AI-generated and wet-lab validated RBP. Industry partners such as the Eliava Institute and Eligo Bioscience have indicated that **3–5 RBPs** are typically required per compassionate-use case, as bacterial populations are often heterogeneous or may mutate during treatment. As a result, a single order can yield gross revenue between **$15,000 and $24,000**, based solely on fixed fees.
2. **Performance-Linked Royalty Structure:** Under breakthrough scenarios, Mystiphage receives an **8% royalty** on net revenues from phage cocktails commercialized using our RBPs. This royalty ensures long-term value capture in the event of breakthrough therapeutic development. For instance, if a Mystiphage-engineered RBP enables treatment of panresistant *P. aeruginosa* – a strain impervious to conventional antibiotics – the resulting phage cocktail may be deployable across broader clinical contexts. In such cases, royalties scale meaningfully with product adoption.

Strategic Rationale

Our combined fee-plus-royalty model delivers immediate cost recovery while promoting long-term partnership alignment. Early-stage labs benefit from affordable entry points for experimental use, while established biotech and CDMO partners retain scalable upside as products reach commercial maturity. This approach supports Mystiphage's financial sustainability through upfront revenues, and rewards shared success via performance royalties—thereby tightly coupling our growth to that of our customers.

Internal Demand Drivers

The demand for personalized RBPs stems from the biological variability of patient infections. Mixed or rapidly mutating bacterial populations require labs to procure multiple RBPs (typically 3–5 per case) to mitigate therapeutic failure. Our pricing reflects the full scope of development, including:

- Proprietary AI modeling
- Wet-lab testing and validation
- Quality control and assurance
- Regulatory and ethical documentation
- Institutional licensing and hospital compliance

Each RBP is not merely a reagent – it is a customized therapeutic prototype ready for bedside translation.

In parallel, many labs view compassionate-use cases as **pre-commercial pilot programs**. Successful treatments generate:

- Real-world performance data
- Foundational proof-of-concept
- Regulatory traction (e.g., IND pathway alignment)

8. Team and Skills

Mystiphage was co-founded by Jaden Bhogal, Lisa Chen, Anthony Dinglasan, Jasmine Jing, Aditya Sakariya and Esha Mohan, whose combined expertise spans research development, operation oversight, business operations and strategy, scientific translation, and interdisciplinary communication. The founding team actively facilitates cross-functional collaboration between scientific and business units, ensuring accurate translation of complex biomedical concepts into actionable business frameworks and entrepreneurial initiatives.

Each co-founder has adopted an immediate vesting schedule of 6% equity. Upon successful completion of the seed financing round in 2026–2027, annual compensation will be CAD $40,000.

Personnel Needs & Expansion Plan

Despite the diverse expertise among the current team, additional talent in AI and computational biology is essential to develop a fully functional proof of concept (POC) and minimum viable product (MVP). Further support is also required in wet-lab operations to validate engineered RBPs and scale therapeutic testing capacity. Following the anticipated seed funding round, Mystiphage plans to onboard four new personnel across each of its wetlab, drylab, and hardware divisions under the larger synthetic biology team. Proposed compensation packages are as follows:

Role	Pre-Seed (Year 0–1)	Seed (Year 1–2)	Series A (Year 3+)	Growth (Year 4+)

AI Specialist ×2	$40K–$55K each (part-time)	$70K–$90K each (full-time, below market)	$100K–$130K each	$120K–$150K each
Operations Manager/Finance	Volunteer or <$50K	$60K–$80K	$90K–$110K	$110K–$130K
Wet-Lab Technicians ×4	$30K–$45K each (stipend/part-time)	$45K–$60K each	$60K–$75K each	$75K–$90K each
Marketing Development Lead	Equity-only or <$50K	$60K–$85K	$90K–$115K	$110K–$140K

The hiring and onboarding process will be managed internally, and no additional overhead costs are expected.

9. Key Resources

To successfully execute our business, we will need the following key physical and digital assets:

1. Datasets of phage-bacteria interactions:

These datasets are critical for training our AI models to predict host range and generate RBP designs.

2. Access to cloud GPUs:

Our dry lab pipeline relies heavily on generative modeling, which requires significant computing resources.

Current provider: AWS
Future plans: Sponsorships, accelerator credits, and scalable paid infrastructure

3. Lab space for experimental validation:

Wet lab validation is critical for testing the efficacy of AI-generated phage proteins against bacterial targets. We have partnered with the University of Toronto's BioZone research facility to access lab space, equipment, and biosafety infrastructure for our experimental workflows.

4. Intellectual property (IP) strategy support:

Safeguarding our core innovations – including engineered RBPs, proprietary datasets, and design algorithms – is a top priority. We are currently working with our mentor from the Hatchery accelerator on early-stage IP planning and intend to engage legal counsel with biotech specialization as we progress toward patent filings and commercialization.

5. Advanced Protein Modeling Platforms:

Mystiphage uses cutting-edge AI tools for structure-aware RBP generation:

- ESM-3 (Meta)

- Boltz-2 (MIT Jameel Clinic and CSAIL, open license)

These platforms enable precise glycan-protein co-folding and masking strategies. While ESM-3 is publicly available through Meta respectively, Boltz-2 developed at MIT's Jameel Clinic and CSAIL in collaboration with Recursion, is released under the MIT Open License, making it freely available for academic and commercial use.

10. Cost Structure

Financial Barriers:

Upfront Costs:

Cost Category	Typical Range (CAD)	Notes
Lab Validation Equipment	~$8,200 CAD	**Heatblocks** ($3.50 – Basic aluminum heat block) **Buckets** ($3.27 – 14L plastic bucket from Walmart) **Electroporator** ($850.00 – Used BTX electroporator) **-20°C Freezer** ($179.99 – Insignia chest freezer) **-80°C Freezer** ($1,099.99 – Frigidaire 24.8 cu. ft. chest freezer) **Tecan Plate Reader** ($294.00 – Used Tecan Infinite F200) **UV Lightbox** ($243.31 – DIY enclosure with 1000W UV light) **Chemidoc Imaging** ($3,000.00 – Used Bio-Rad ChemiDoc MP) **Thermocyclers (x5)** ($1,870.00 – Bio-Rad Tetrad 2 with 4 blocks; ~$374.00 each) **Pipetting Robot** ($72.00 – Used Artel PCS2 system) **Tabletop Centrifuge** ($97.92 – 6x20ml benchtop centrifuge) **Laboratory Analog Incubator** ($955.50 – Solid steel door, 0.7 cu. ft. capacity)

Fixed Costs Annually (year 1):

Cost Category	Typical Range (CAD)	Notes
Documentation -Related Costs	~$80,000	Provisional patent ($12,000), licensing and royalty agreement setup ($10,000), international compliance and review ($15,000), compassionate use documentation ($6,000), legal counsel ($30,000), Incorporation Expense ($5,000)
Lab Space	~$7,000	BSL-2 Wet Lab ($4,000–$7,000/month) Includes: - HVAC - biosafety cabinets - access to shared amenities
Lab Consumables	~$3,200	**Eppendorf Tubes [100x1.5mL]** ($76.50) **Glass Vials [12x30mL]** ($14.38) **Pipette Tip Box [empty]** ($8.12) **Monarch® Spin PCR & DNA Cleanup Kit** ($102.00) - Monarch® Buffer - BZ Monarch® - Buffer WZ Monarch® - Buffer EY Monarch® Spin **Plasmid Miniprep Kit** ($77.25) - Monarch® Buffer - B1 Monarch® - Buffer B2 Monarch® - Buffer B3 Monarch® **RNase A Gibson Assembly Master Mix** ($134.25) **NAD+ [caps**] ($35.82) **PEG-8000 [500 g**] ($420.56) **Tris-HCl [500 g**] ($66.00) **$MgCl_2$ [25 kg flakes]** ($258.75) **Ni Resin [5 mL]** ($112.50) **NEBridge® Golden Gate Assembly Kit [BsaI-HF® v2]** ($133.50) - T4 DNA Ligase Reaction Buffer NEBridge® - Golden Gate Enzyme Mix (BsaI-HFv2) - pGGAselect DNA - NEB 2X Master Mix 500 reactions - Hot Start Taq 2X Master Mix

Variable Costs Depending on # of RBPs (1st Year):

Cost Category	Typical Range (CAD)	Notes
Salary	~$200,000	Based on lean pre-seed hiring: AI Specialist x2(<$40K), Wet-Lab Technicians ×4 (<$30K), Marketing Lead (equity-driven, no salary), Finance/Operations Lead (volunteer/part-time). Most roles accept reduced pay or equity in Year 0–1 to conserve cash runway. Will increase overtime as business grows.
Data Acquisition	$2,000–$5,000	Includes sourcing bacterial isolate data, receptor annotations, and metadata
Storage & Management	$1,000–$5,000	Cloud storage, backups, and version control systems
Model Monitoring & Updates	$5,000–$10,000	Covers retraining, performance tracking, and bug fixes
Security and Compliance	$2,000–$8,000	Ensures data privacy
Reagents	$1,500	**BsaI** ($72) **DpnI** ($88) **NcoI** ($48) **HindIII** ($43) **NheI** ($58) **CutSmart Buffer** ($42) **T4 Ligase** ($89) **T4 PNK (Polynucleotide Kinase)** ($89) **T4 Ligase Buffer** ($42) **Mitomycin C** ($245) **DNA Base Pairs** ($360) **Guide rRNAs** ($90) **Calcium Competent Cells ($CaCl_2$, Glycerol)** ($89) **dd$H_2O$** ($58) **Ethanol (C_2H_6O)** ($90) **Bleach** ($6)

Year 1 (incl. Upfront Cost) Total Estimated Range: Approximately $359,700. This assumes moderate usage, lean infrastructure, and a focused application scope. This estimate is expected to scale proportionally as Mystiphage expands its customer base

and increases market penetration. In Years 2+, upfront costs are not included in the cost breakdown.

Taxes Breakdown

Component	Rate or Credit Applied	Notes
Federal Corporate Tax (after SBD)	9.0%	On first $500K of active business income
Ontario Corporate Tax (Small Biz)	3.2%	For small businesses under $500K taxable income
Combined Base Rate	~12.2%	Typical small business corporate rate in Ontario
Federal SR&ED Credit	35% (on eligible expenditures)	Refundable; reduces payable or increases refund
Ontario SR&ED Credit	3.5% (non-refundable)	Applies to same eligible R&D expenses
Effective Tax Rate (after credits)	~4.5% – 6%	Depending on R&D intensity, salaries claimed, and carryforwards

AI Optimization to Offset Cost:

Mystiphage is actively optimizing its AI maintenance costs through strategic hardware and data-driven efficiencies. Our models are trained across distributed GPU clusters, dramatically accelerating computational throughput while maximizing resource utilization. Once training is complete, the system transitions into a lightweight inference mode—delivering high-precision predictions at a fraction of the original processing demand.

Beyond hardware efficiency, Mystiphage is building a dynamic generative phage library: as wetlab and drylab teams validate RBP-phage pairings per patient case, these combinations are archived for reuse. If future patients present bacterial receptors already catalogued, we bypass full AI redeployment and proceed directly to wetlab testing—streamlining turnaround and cutting costs. While RBPs are typically patient-specific, receptor overlap across cases allows previously validated modules to serve as fast, low-cost therapeutic options. This hybrid approach ensures computational sustainability while scaling precision therapeutics.

Lab Discounts for Wet-Lab Validation Material:

Since Mystiphage is formally recognized as a research laboratory, our wet-lab validation team will receive institutional discounts on most scientific reagents, equipment, and consumables. These discounts can vary depending on the supplier, volume, and product category — typically ranging from 10% up to 40%. This allows us to reduce costs significantly while maintaining high-quality standards for wet-lab validation.

Base Financial Case Breakdown: Year 1

Assuming we sell a mean of 4 RBPs per client at an average fee of $12,000 with $3000 per RBP, with 5 clients, our Year 1 gross revenue is projected at **$60,000.** Deducting operational costs ($359.7K), taxes at 12.2%, the estimated net profit is $35.3K. In Year 2, gross revenue is projected to be **$180K**, with operational costs to be $384.7K, resulting in net loss of **$204.7K**. The materials and supplies are expected to increase by 2% inflation from Year 2. (*Refer to our cashflow excel sheet for more details)

Scenario 1: Base Financial Case: First Five-Year Financial Plan

Year	Customers	RBPs Sold	Revenue	Operational Costs	Net Profit (After 12.2% Tax)
1	5	20	$400.0K	$359.7K	$35.3K
2	15	60	$1.2M	$384.7K	$715.8K

3	30	120	$2.4M	$315.3K	$1.830M
4	60	240	$4.8M	$321.6K	$3.932M
5	100	400	$8.0M	$328.0K	$6.736M

Assumptions:

- **Base RBP Sales Revenue**: $5,000 per unit
- **Operational Costs**: Scale proportionally per year based on overall sales volume
- **Tax Rate**: Fixed at **12.2%,** excluding SR&ED credits and Ontario small business deductions
- **Compassionate case count:** 1 per customer per year
- All currency is in CAD
- No medical breakthroughs impacting royalties

Net profit after tax (5 years): Approximately **$13.2M** CAD**.**

Scenario 2: Twelve-Year Financial Plan (Assuming Year 2 Customer Breakthrough)

Year	Customers	RBPs Sold	Base Revenue	CC*	Royalty Revenue	Gross Revenue	Phase Trial Cost	IP Cost	Net Profit (Post OpEx* and Tax)
1	5	20	$690K	5	$1.6K	$691.6K	–	–	$341K
2	15	60	$2.07M	15	$4.8K	$2.08M	$900K (Pre-Cl.*)	–	$630K
3	30	120	$4.14M	30	$9.6K	$4.15M	$1.58M (Ph I*)	$50K	$1.89M
4	60	240	$8.28M	60	$19.2K	$8.30M	$5.55M (Ph II*)	$50K	$2.00M
5	100	400	$13.8M	100	$32K	$13.83M	–	$50K	$7.97M
6	105	420	$14.49M	105	$33.6K	$14.52M	$5.7M (Ph III*)	–	$7.32M
7	110	440	$15.18M	110	$35.2K	$15.22M	–	–	$12.90M
8	115	460	$15.87M	115	$36.8K	$15.91M	–	–	$13.48M

9	120	480	$16.56M	120	$38.4K	$16.60M	–	–	$14.05M
10	125	500	$17.25M	300K	$96M	$113.25M	–	–	$98.98M
11	130	520	$17.94M	500K	$160M	$177.94M	–	–	$155.74M
12	135	540	$18.63M	700K	$224M	$242.63M	–	–	$212.50M

We have not included breakthrough cash flow projections in the Cash Flow Projections Excel, as numerous extraneous variables—such as clinical trial costs—introduce significant uncertainty. While we can provide general estimates in the Business Plan, these factors prevent us from producing precise calculations for the Cash Flow Projections.

We assume that the price of the RBPs and the royalties from the break though would not change significantly. We also assume that after year 5 the change in operational costs would remain constant or negligibly different.

Assumptions:

***Terms:**

- CC = Compassionate Cases
- OpEx = Operational Expenses
- Ph = Phase (ex: Ph I = Phase I)
- Pre-Cl. = Pre-Clinical Trials
    - Includes GLP compliance, protocol development, formulation testing

Drug Development & Clinical Assumptions

- **Year 2 Breakthrough Discovery**: Breakthrough phage therapy is discovered in Year 3 and enters the clinical pipeline.

- **8-Year Clinical Trial Timeline**:
    - **Pre-Clinical Trials:** Starts in Year 2, lasts **1 year**, cost = **$3M,** Mystiphage's share = **$900K** (Ledesma, 2024)
    - **Phase I**: Starts in Year 3, lasts **1 year**, cost = **$5.26M**, Mystiphage's share = **$1.58M** (Abacum, 2020)
    - **Phase II**: Starts in Year 4, lasts **2 years**, cost = **$18.49M**, Mystiphage's share = **$5.55M** (Abacum, 2020)
    - **Phase III**: Starts in Year 6, lasts **4 years**, cost = **$19M**, Mystiphage's share = **$5.7M** (Afschin Gandjour, 2024)
- Mystiphage funds 30% of clinical trial costs (the remaining 70% is the responsibility of breakthrough customer company)

Intellectual Property & Licensing Assumptions

- **Patenting/IP Costs**:
    - Annual cost = **$100K**, Mystiphage's share = **$50K/year** in Years **3–5**
- Mystiphage funds 50% of Patenting/IP costs (the remaining 50% is the responsibility of breakthrough customer company)
- **Royalty Agreement**:
    - Mystiphage earns **8% royalty** from **compassionate case sales**
    - Each case priced at **$4,000**

Financial & Operational Assumptions

- **Base RBP Sales Revenue**: $34,500 per unit
- **Operational Costs**: Scale proportionally per year based on overall sales volume
- **Tax Rate**: Fixed at **12.2%**
- We assume that the price of the RBPs and the royalties from the break though would not change significantly.
- We also assume that after year 5 the change in operational costs would remain constant or negligibly different.
- All currency is in CAD

Market Uptake & Growth Assumptions

- Gradual growth in customers and RBP sales from Year 1 to Year 9
- Massive surge in **compassionate case volumes due to breakthrough treatment**:
    - Year 10: **300K cases**
    - Year 11: **500K cases**
    - Year 12: **700K cases**

Phage Therapy Price Assumption

- Projections assume patient price for phage therapy remains constant over the 12-year timeframe.

Inflation Rate:

- Assumes 2% inflation rate on costs annually.

Net profit after tax (12 years): Approximately **$528.77M** CAD.

11. Key Partners

We rely on a few critical suppliers that provide essential infrastructure for our dry lab development:

Cloud Compute Providers

These companies supply the GPU computing power we need to train and deploy AI models for RBP design. Their core business is providing scalable cloud infrastructure and services. We're pursuing research credits (e.g., AWS, Lambda, labs) to initiate a relationship and demonstrate loyalty through consistent usage, case studies, and potential co-branding opportunities. As we scale, we plan to negotiate preferential rates or credits through accelerator programs. While we will begin with a single provider for simplicity, we may diversify across cloud platforms to optimize performance and pricing.

Software Tool Developers (e.g., Boltz-2, ESM3, BindCraft)

These tools are developed by academic or industrial research groups and provide critical generative capabilities in our modeling pipeline. While not conventional "suppliers," they form the backbone of our dry lab infrastructure. BindCraft and Boltz-2 are open-source projects with permissive licenses, while ESM-3 is made available for research use under a more restricted license. We ensure license compliance, credit the developers in our materials, and stay active in relevant research communities. Over time, we may seek collaboration with tool maintainers or contributors to extend capabilities aligned with our specific design goals.

Potential Future Key Partners

We've identified key academic and institutional partners whose support would be essential for execution and validation:

Davidson Lab & Maxwell Lab

Affiliation: University of Toronto
Focus: Phage biology and host-pathogen interactions
Location: Toronto, Canada

- Value to us: Would supply curated datasets, relevant experimental advice, and scientific credibility via partnership.
- Value to them: Through partnership, they can access our AI models and generative RBP bank to support their own research efforts. This could enable potential co-publication opportunities and strengthen the translational impact of their work.
- Partnership Strategy: Shared advising relationships and ongoing collaboration, to be formalized through research MOUs or joint grant applications.

BioZone

Affiliation: University of Toronto

Focus: Interdisciplinary synthetic biology and bioengineering

Location: Toronto, Canada

- Location: Toronto, Canada
- Value to us: Provides physical lab space, safety infrastructure, and access to shared equipment
- Value to them: Our work aligns with BioZone's mission to support biotech innovation and offers potential for showcasing impactful student-driven ventures.
- Partnership Strategy: Faculty mentorship, to be formalized via facility access agreements and biosafety training compliance.

The Hatchery

Affiliation: University of Toronto

Focus: University-based entrepreneurship incubator

Location: Toronto, Canada

- Value to us: Provides business mentorship, IP strategy advice, pitch practice, and investor connections
- Value to them: We contribute to their portfolio of high-potential student ventures and provide success stories for institutional impact reporting.
- Partnership Strategy: Participation in formal programs, 1-on-1 mentorship, and regular reporting to demonstrate progress.

Long Term Future Partner Goals

As Mystiphage becomes more established with experience and customer base (and as phage therapy becomes more adopted by large-scaled pharmaceutical companies), we will aim to collaborate with companies like IPATH, Eligo Biosciences, and Eliava Institute in expediting their research workflow.

12. Execution and Timeline

Key Milestones + Timeline

- Build Alpha Version of Mystiphage AI Platform
    - Timeline: Y1 Q1-Q2
    - Deliverables: Core generative AI model trained on E. coli phage–host interaction datasets
    - Assigned to: iGEM Drylab Team
- Wet Lab Pipeline Setup for Sequence Validation
    - Timeline: Y1 Q2-Q3
    - Deliverables: Protocols for RBP validation, sequencing, and phage matching
    - Assigned to: iGEM Wetlab Team

- Secure Biobank and Bacterial Strain Access
    - Timeline: Y1 Q3
    - Deliverables: Agreement with biotech or university strain suppliers
    - Assigned to: Anthony (Partnerships Lead)

2. Research and Data Acquisition

- Curate Public and Clinical Bacterial Genomes
    - Timeline: Y1 Q1-Q2
    - Deliverables: AI-ready datasets from public repositories
    - Assigned to: iGEM Drylab Team
- Benchmark Existing RBP Design Models
    - Timeline: Y1 Q1-Q2
    - Deliverables: Comparative report for validation
    - Assigned to: iGEM Drylab, Hardware & Wetlab Team

3. Customer Acquisition & Outreach

- Stakeholder Interviews & Early Adopter Pipeline
    - Timeline: Y1 Q3 - Y2 Q1
    - Deliverables: Targeted list of candidate labs and researchers
    - Assigned to: Lisa & Jasmine (Marketing & External Relations)
- Engage targeted institutions and industry players in exploratory discussions for pilot programs and early collaborations. Progress these conversations toward Letters of Intent and partnership agreements
    - Timeline: Y1 Q3 - Y2 Q4
    - Deliverables: Letters of Intent or formal agreements with institutions or industry participants
    - Assigned to: Lisa (Strategy & Funding)
- Launch MVP Outreach Campaign

    - Timeline: Y2 Q2
    - Deliverables: Email outreach, social engagement, professional announcements
    - Assigned to: Jaden & Lisa
- Close First Customer Agreement
    - Timeline: Y2 Q2
    - Deliverables: Signed deal and product delivery schedule
    - Assigned to: Anthony & Esha & Lisa

4. Skill Development

- AI-Clinical Integration Training Sessions
    - Timeline: Y1 Q2-Q3
    - Deliverables: Regulatory workshops on health data usage and sensitivity
    - Assigned to: Jaden (Regulatory & Compliance) & iGEM Advisory Team
- Wet/Dry Lab Collaboration Training
    - Timeline: Ongoing during Y1 Q1-Q4
    - Deliverables: Standardized handoff procedures and lab-data coordination
    - Assigned to: Wetlab, Drylab, and Hardware lead.

5. Intellectual Property

- File Provisional Patent for Generative RBP Design
    - Timeline: Y1 Q4
    - Deliverables: Submitted patent application covering core methods
    - Assigned to: Anthony & Esha & Lisa
- Trademark Mystiphage Platform & Branding
    - Timeline: Y1 Q2 - Q3
    - Deliverables: Trademark filing with CIPO

    - Assigned to: Jasmine, Anthony, Lisa, Aditya, and Esha (Branding Team)

6. Risk Consideration

- Risk Mapping & Mitigation Strategy
    - Timeline: Y1 Q2 - Y2 Q1
    - Deliverables: Establish strategic foresight around regulatory, IP, scientific validation, funding runway, etc
    - Assigned to: Lisa

Summary Timeline:

Timeline	Milestone Highlights
Y1 Q1-Q2	AI model training, genome curation begins
Y1 Q2-Y2 Q2	Wetlab setup, branding filings, team workshops, risk mapping & mitigation
Y1 Q3-Y2	Biobank secured, outreach prep, stakeholder input, early adopter outreach and strategic partner conversations initiates
Y1 Q4-Y2	Patent filing, alpha platform + wetlab connection
Y2 Q1	MVP campaign launches, customer engagement begins
Y2 Q2	First customer signed and validated delivery begins

Execution Timeline

Mystiphage Execution and Timeline - Google Sheets

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