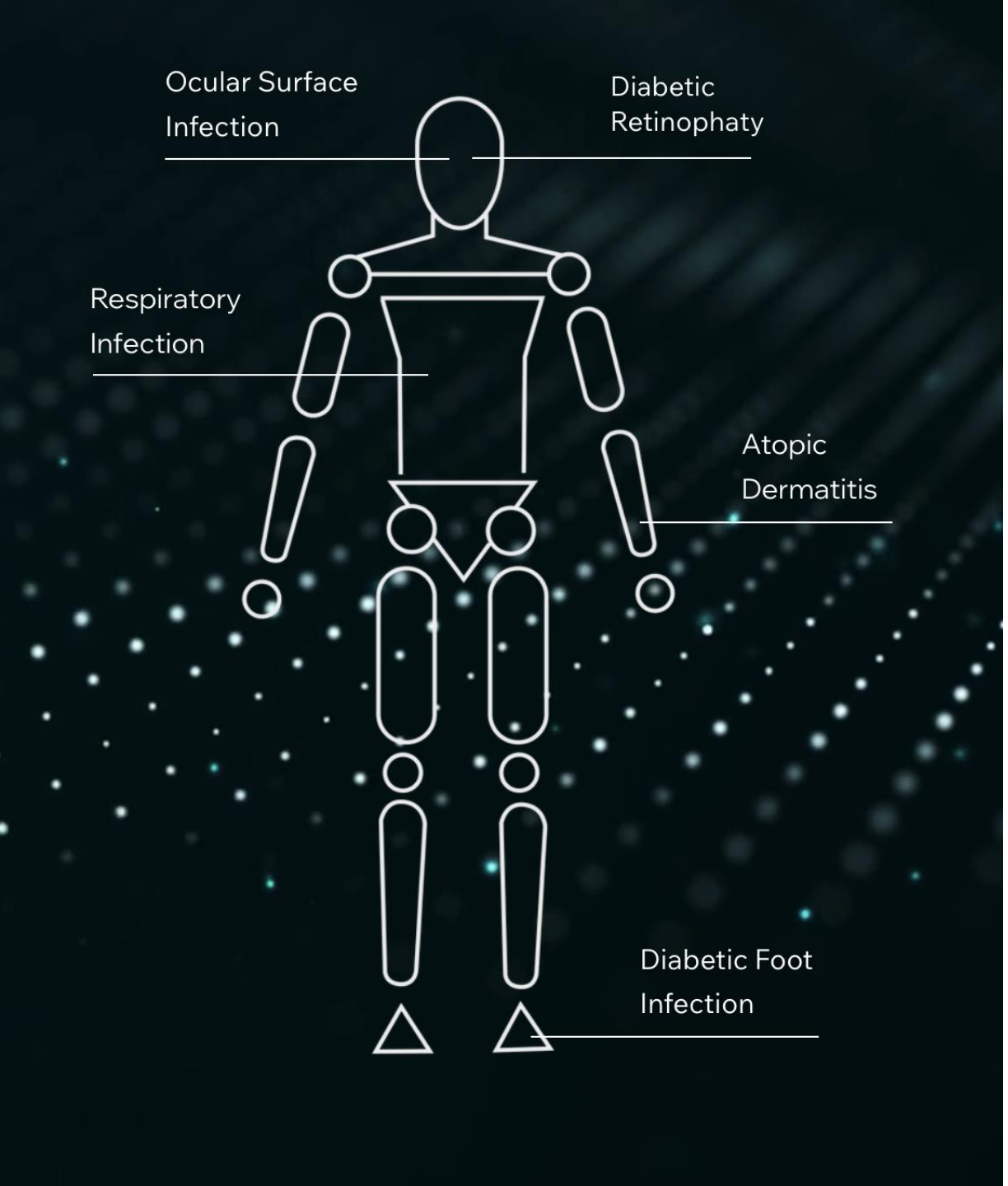


Bio Innovation is Our Mission

We are biotechnology pharmaceutical company focusing on antibody and bacteriophage therapies to address unmet medical needs.

Our cutting-edge research aims to develop novel treatments for resistant infections and complex diseases, providing new hope for patients.

LX bio Pharmaceuticals

About us

New Biopharmaceutical Company

We are developing several biological products for the treatment of unmet medical needs, for:

Diabetic foot infections, diabetic retinopathy, glaucoma, dry eye, atopic dermatitis, pneumonia, Ventilator-Associated and other medical conditions.

We had discovered, engendering and developed several **NEW biological pharmaceutical products** for unmet medical needs:

Bacteriophages Technology for Human, animal and industrial application

Small antibodies for for Human and animal application

In “situ” slow-release drug delivery devices

OUR MISSION

To be a global player in biotechnology, with a special focus in the phage therapy. We aim to develop several biotechnological solutions that will revolutionize the treatment and prevention of diseases, improving the quality of life for individuals across the globe in a sustainable way.

OUR VISION

To be recognized not only for our scientific achievements but also for our unwavering dedication to ethical and responsible biotechnological advancements. We aim to inspire a new era of healthcare, where the power of biotechnology is used responsibly, ethically, and with a profound commitment to the well-being of both current and future generations.

OUR VALUE PROPOSITION

- R&D NEW Biopharma Products
- Licensing and distribution our products WW
- CDMO & CRO production and R&D unit

LX bio Pharmaceuticals

A GLOBAL Problem

Antimicrobial resistance (AMR)

or multi-drug resistance

According to a published report (Antimicrobial Resistance, 2022), antimicrobial resistance is a major public health concern.[1]

1.27 Million
global deaths in 2019[1]

US$ 1 Trillion
additional healthcare costs by 2050[1]

AMR is one of the top global public health and development threats.[1]

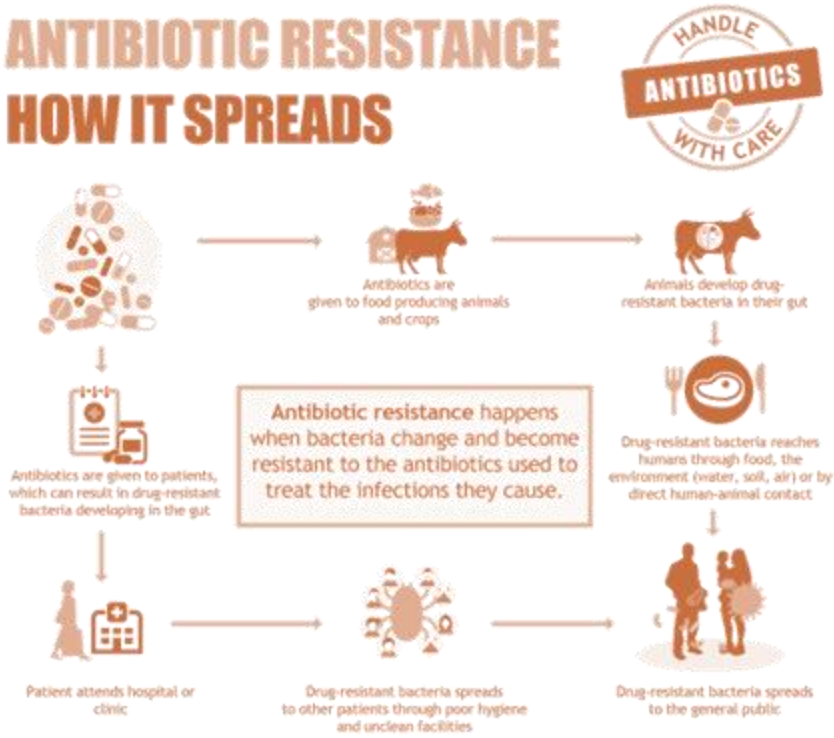
Overuse of antimicrobials in humans, animals and plants.[1]

AMR affects countries in all regions and at all income levels.[1]

AMR puts many of the gains of modern **medicine at risk.**[1]

The world faces an **antibiotics pipeline crisis.**[1]

In addition to death and disability, **AMR has significant economic costs.**[1]



1. World Health Organization Website. Accessed 08/03/24. https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance

LX bio Pharmaceuticals

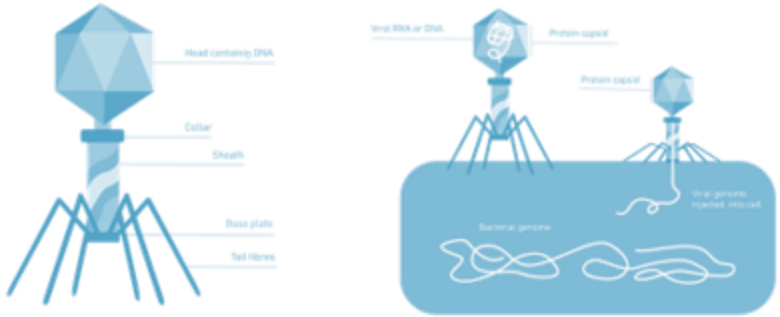
A Solution Phage Therapy

The technology involves naturally occurring and genetically modified phages combine in a cocktail of lytic bacteriophages to specifically target the bacteria causing the infections, means that each phage has only a specific host target.[2]

Are a promising solution against antimicrobial resistance (AMR) or multi-drug resistance

Phages are Bacteria's Natural Predator

Phage therapy is now considered a potent weapon for eradicating MDR bacterial strains and combating refractory infections.



Bacteriophages selectively target and infect bacteria.[1]

Advantages over conventional antibiotics.[2]

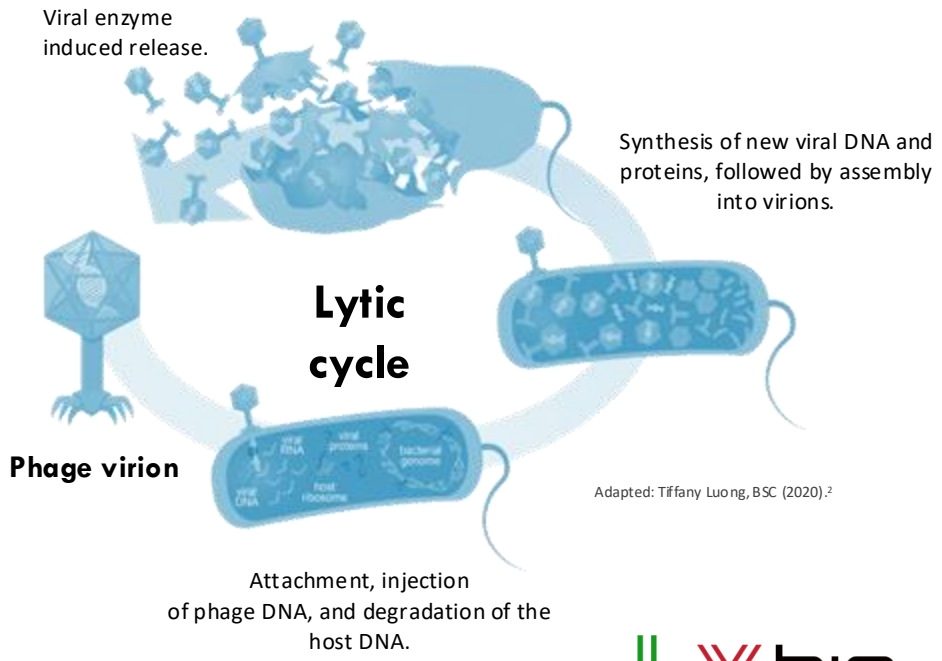
High level of specificity. Target a particular bacteria.[2]

Harmless to other organisms, including humans.[2]

Effectively fight and destroy multi-drug resistant bacteria.[2]

When all antibiotics fails,

phages still succeed in killing the bacteria and may save a life from an infection.



1. Matthew J. Young (2023). Phage Therapy for Diabetic Foot Infection: A Case Series. Elsevier. https://doi.org/10.1016/j.clinthera.2023.06.009
2. Jo, S.J.; Kwon, J.; Kim, S.G.; Lee, S.-J. The Biotechnological Application of Bacteriophages: What to Do and Where to Go in the Middle of the Post-Antibiotic Era. Microorganisms 2023, 11, 2311. https://doi.org/10.3390/ microorganisms11092311

LX bio Pharmaceuticals

Phages comparison to antibiotics

Phage therapy aims to do the same thing as antibiotics in treating bacterial infections, although they have different mechanisms

Advantages

Phages cannot grow without their target bacteria.

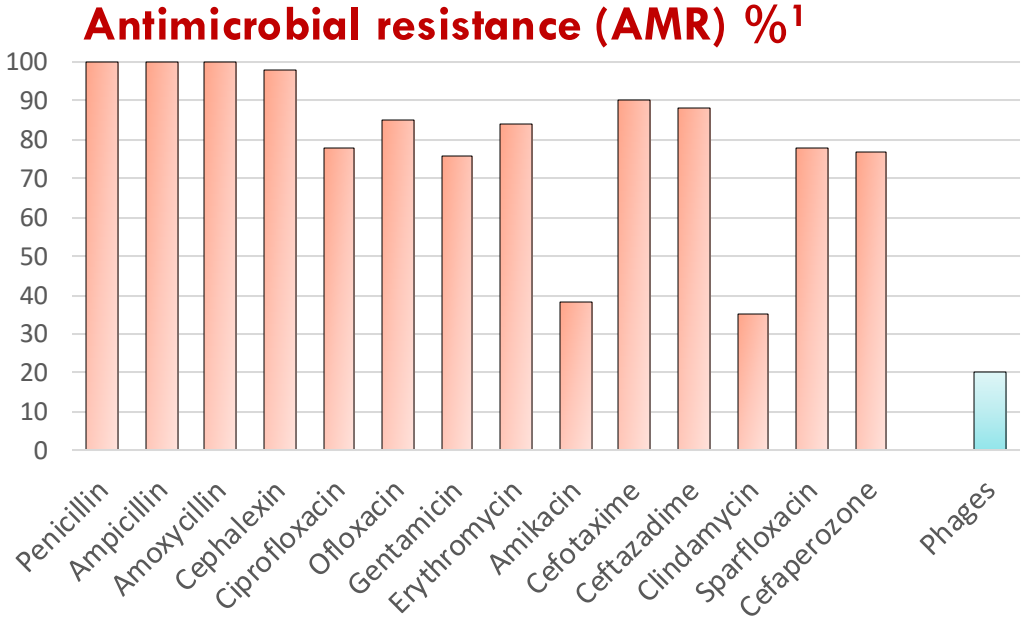
Once they killed the pathogen, they too will die.

Easy to administer orally, intravenously, or topically.

High specificity reduces the potential for secondary infections.

Specificity of phages makes them less toxic than some antibiotics.

Antibiotics often have a problem reaching bacterial targets.



Graph of the percentage of MRSA strains,
isolated from hospitalized diabetic patients,
that are resistant to various antibiotics and therapies.
Source: modified from data presented by Kvachadze et al.

1. Kvachadze L., Balarjishvili N., Meskhi T., Tevdoradze E., Skhirtladze N., Pataridze T., Adamia R., Topuria T., Kutter E., Rohde C., and Kutateladze M. "Evaluation of lytic Activity of Staphylococcal Bacteriophage Sb-1 Against Freshly Isolated Clinical Pathogens" Microbial Biotechnology, 2011, Volume 4, Issue 5, p.643-650.

LX bio Pharmaceuticals

Pipeline

Program/Product	Area	Disease	Product	TRL 1	TRL 2	TRL 3	TRL 4	TRL 5	TRL 6	TRL 7	TRL 8	TRL 9	Approval	Timeline
Topical Bacteriophages cocktail Diabetes	Internal medicine and orthopaedics	Diabetic foot infection	TP102										Q1 2027	2024 - Q1 27
Eyedrops encapsulated Anti-VEGF	Ophthalmology	Macular Degeneration & Diabetic retinopathy	LX24OP02										Q2 2027	2024 - Q2 27
Aerosol Respiratory infection	Hospital intensive care	Hospital Acquired Pneumonia	TP122										Q1 2028	2024 - Q1 28
Eyedrops Bacteriophage	Ophthalmology	Blepharitis & Ocular infection	LX24OP01										Q2 2029	2024 - Q2 29
Topical Bacteriophage plus corticoid	Dermatology	Atopic Dermatitis	LX24DE01										Q1 2027	2024 - Q1 27
In situ gel drug delivery system - extended release	Ophthalmology	Several drugs	LX24OP05										Q1 2029	2024 - Q1 29

TRL1 *Review of Scientific Knowledge Base*
TRL2 *Development of Hypotheses and Experimental Designs*
TRL3 *Target Identification and Characterization of Preliminary Candidate(s)*
TRL4 *Candidate Optimization and Non-GLP In Vivo Demonstration of Activity and Efficacy*
TRL5 *Advanced Characterization of Candidate and Initiation of GMP Process Development*
TRL6 *GMP Pilot Lot Production, IND Submission, and Phase 1 Clinical Trial(s)*
TRL7 *Scale-up, Initiation of GMP Process Validation, and Phase 2 Clinical Trial(s)*
TRL8 *Completion of GMP Validation and Consistency Lot Manufacturing, Pivotal Animal Efficacy Studies or Clinical Trials, and FDA/EMA Approval or Licensure*
TRL9 *Post-Licensure and Post-Approval Activities*

LX CRO biologics

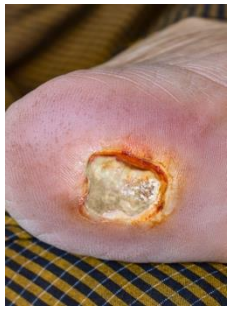
TP-102 product for Diabetic Foot Infection

The PROBLEM: Diabetes prevalence is growing

DFUs are serious complications of diabetes, resulting in significant morbidity and mortality.[2]

Bacterial agents causing diabetic foot ARE increasing antibiotic resistance.

Difficulty in treating (AMR) the condition contributes to a higher risk of amputation and mortality.



1/3 of Patients with diabetes **develop DFU.**

20% Patients with infected DFU **require amputation.**

5% Patients with DFU (amputations) **die within 12 month.**

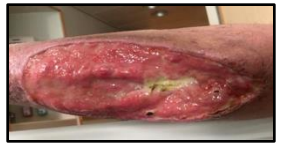
42% Patients with DFU (amputations) **die within 5 years.**

The SOLUTION

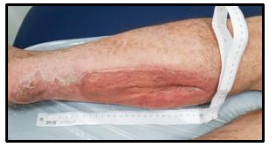
Our product is an innovative bacteriophage cocktail comprised of 5 lytic bacteriophages against 3 major bacteria's present in the DFI:

Staphylococcus aureus	*Pseudomonas aeruginosa*	*Acinetobacter baumannii*

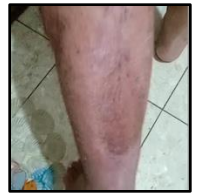
REAL LIFE EVIDENCE Results from a compassion use program



Start
phage therapy



Two months
post phage therapy



Six months
post phage therapy recovered

STAGE OF DEVELOPEMENT

It has received Fast Track Designation from the FDA

And is is currently on:

PHASE IIb Human Clinical Trials

ON-GOING

to determine safety and efficacy, in patients with DFI.

CURRENT Formulation
1% HPMC **hydrogel**

Expect to Close January 2025

R&D ROAD MAP

PHASE III Human Clinical Trials

Manage by Lxbio

Expect

APPROVAL MARKET INTRODUTION Q1 2027

LXbio Pharmaceuticals

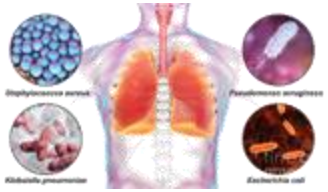
TP-122 product for Nosocomial Pneumonia

The PROBLEM: VAP Bacteria Resistant

Ventilator-Acquired Pneumonia (VAP), results from the invasion of the lower respiratory tract and lung parenchyma by microorganisms. VAP results from the invasion of the lower respiratory tract and lung parenchyma by microorganisms.

Resistant bacteria might be present in early-onset VAP.

Acinetobacter baumannii, Pseudomonas aeruginosa, and methicillin-resistant Staphylococcus aureus (MRSA) were the most frequent causative microorganisms for VAP.



2nd most common hospital-acquired infection

VAP mortality 25% - 50%

it may increase to 70% in some cases.

The SOLUTION

Our product is a cocktail, composed by **6 different phages**, developed for the treatment of VAP targeting two species.

6 bacteriophages to maximize host range.

Targets two critical pathogens at once.

Applied using vibrating mesh nebulizers.

Every 8 hours, for 7 days.

STAGE OF DEVELOPEMENT

PHASE I/IIa Human Clinical Trials

APPROVED.

A randomized, parallel, open-label, Phase I/IIa study to assess the safety and tolerability of multiple doses of the bacteriophage cocktail TP-122, for the treatment of Ventilator-Associated Pneumonia.

R&D ROAD MAP

Expect to Start Q1 2025

2025	2026-27	Q1 2028
Clinical Trials Phase1/2	Clinical Trials Phase 3	Submission & approval

LX bio Pharmaceuticals

LX24DE01 product for Atopic Dermatitis

The PROBLEM: Staphylococcus Aureus Bacteria Resistant

AD **is a chronic, immune-mediated disease currently incurable**, determined by the interaction of genetic and environmental factors.

AD has a profound influence on all aspects of quality of life.

Affects up to **25%** of children and **10%** of adults.

There is no cure

80% of patients with AD presented colonization with Staphylococcus aureus

Treatments **only treat the symptoms**
Lesions are often treated with **topical corticosteroids**.

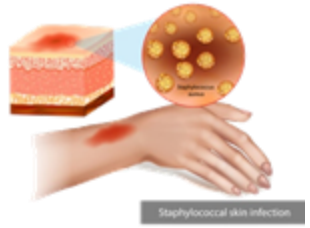
The SOLUTION

Our product is a novel topical fixed combination of **antibacterial phage cocktail composed by 2 different phage's** having a high specificity against Staphylococcus Aureus plus **a corticosteroid** for treatment of **atopic dermatitis**.

Bacteriophages

Address Skin infections

Cause because of bacterial, viral, fungal, and parasitic.



Corticoid

Address Skin inflammation

A sign of an immune response in the body.
Many potential causes, including allergies, infections, and autoimmune diseases.

STAGE OF DEVELOPEMENT

Prove of concept

Pre-Clinical Trials
to determine efficacy on Skin infections due to Staphylococcus Aureus

R&D ROAD MAP

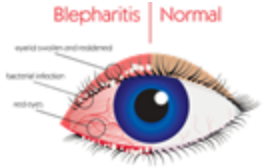
Hybrid application based on established use (API over 10 Y)

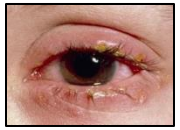
2024	2025	2026	FDA/EMA Q1 2027
Proof of concept Formulation	Pre-clinical studies	Clinical Trials Phase 2/3	**Submission & approval**

LX24OP01 product for Blepharitis

The PROBLEM: Antibiotic Bacteria Resistant

Ophthalmologic condition characterized by an inflammation of the eyelid margins. It can be acute or chronic.



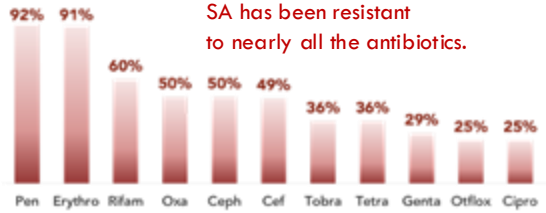


The cause is most likely multifactorial.
Combination of chronic low-grade bacterial infections.
Parasitic infestations with Demodex mites.

Staphylococcus aureus (SA)

is a well-known ocular pathogen and account for the majority of bacterial ocular infections.

No novel ocular antibiotics have entered the market



The SOLUTION

Our product is an **antibacterial phage cocktail in eye drops solution** with high specificity to control of bacterial infections in the ocular surface of the eye, including conjunctiva, eyelids, eyelashes, glands and particularly in Blepharitis.

LXF2000 **4** bacteriophages cocktail

With a high specificity against:

Bacteria
Staphylococcus aureus

Bacteria
Pseudomonas aeruginosa

Eye drops
preservative free container.

Saline ophthalmic solution
eye drops 10 ml.

STAGE OF DEVELOPEMENT

Prove of concept

Pre-Clinical Trials

to determine efficacy against Staphylococcus aureus and Pseudomonas aeruginosa present in the ocular surface.

R&D ROAD MAP

2024	2025	2026-2028	FDA/EMA
Proof of concept Formulation	Pre-clinical studies	Clinical Trials Phase 1/2/3	**Q2 2029** Submission & approval

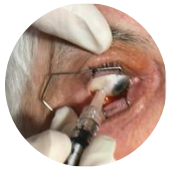
LX24OP02 product for Diabetic Retinopathy

The PROBLEM: Diabetes prevalence is growing

Diabetic macular oedema (DME) and Age-related macular degeneration (AMD), are two main causes of blindness due to the accumulation of excess fluid in the extracellular space within the retina in the macular area.

Current therapy are intravitreal injections with several complications

Infection in the eye.
Endophthalmitis.
Bleeding into the vitreous gel.
Retinal detachment.
Elevated intraocular pressure.
Long-term structural.



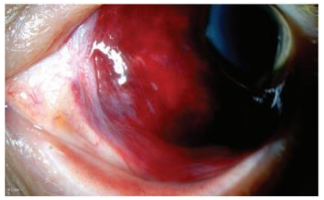
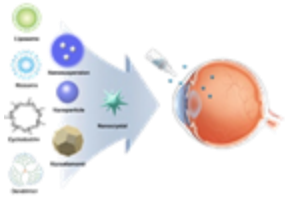


Figure 2
Chemosis or swelling of the conjunctiva with sub-conjunctival hemorrhage. Jason S. Calhoun, Retina Image Bank, 2013; Image 7720. © American Society of Retina Specialists.

Intravitreal injections **often need to be repeated in chronic conditions** *such as AMD, diabetic macular edema, and retinal vein occlusions.*

The SOLUTION

Our product consists in a **NEW single domain antibody** with high expression. The small molecular weight has affinity of conventional antibody (anti-VEGF) but a higher solubility allow to be delivered to the **eye in an eyedrops solution**.



The technology consists to **encapsule the anti-VEGF antibody in a nano liposome particle** that allows the product **in eyedrops to reach the retina** (back of the eye)

"this product will change the paradigm of DR treatment"
Dr. José Dias - Ophthalmologist

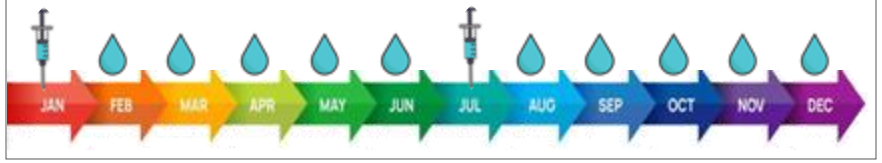
This is highly convenient to the patient and to the doctor
No Eye pain, risk or discomfort.
No repeat injection.
Less cost to the patients and healthcare systems

STAGE OF DEVELOPEMENT

Prove of concept

Pre-Clinical Trials
to determine efficacy on the retina neovascularization

Protocol treatment per patient
Macular degeneration or Diabetic Retinopathy



R&D ROAD MAP

Hybrid application based on established use (API over 10 Y)

2024	2025	2026	FDA/EMA
Proof of concept Formulation	Pre-clinical studies	Clinical Trials Phase 2/3	**Q2 2027** **Submission & approval**

NEW Biopharmaceutical

Research and Development
Production Unit

Oeiras | Lisbon | Portugal

Designed to meet **both production and R&D goals.**

Latest state-of-the-art equipment and technology.

Segregated areas for manufacturing and I&D.

Good Manufacturing Practices **(GMP).**

Robust **quality control** and quality assurance systems.

ESG policies and procedures

What?

New Research
and Development
Production Unit

Why?

High demand
and low offer for CRO
and CDMO services
for Monoclonal Antibodies

How?

Designed for
Monoclonal Antibodies
Antibody discovery and engineering

Aligned with Lxbio new pipeline

Offering CRO & CDMO services

When?

Ready in
QRT3'26

LX CRO biologics

THANK YOU
FOR YOUR TIME

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lxbio.pt