# PHAX AM

# PHAXIAM

# Building a Global Leader in Severe Infections Therapies

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# Agenda

- 1. Global Context
- 2. PHAXIAM Differentiation
- 3. Development Strategy
- 4. Communication & Financing



# Experienced & Complementary Leadership Team

Thibaut du Fayet CEO



Pascal Birman, MD CMO



Frédéric Mathat CFO





Jérôme Bailly CQO / CTO



Cindy Fevre CSO

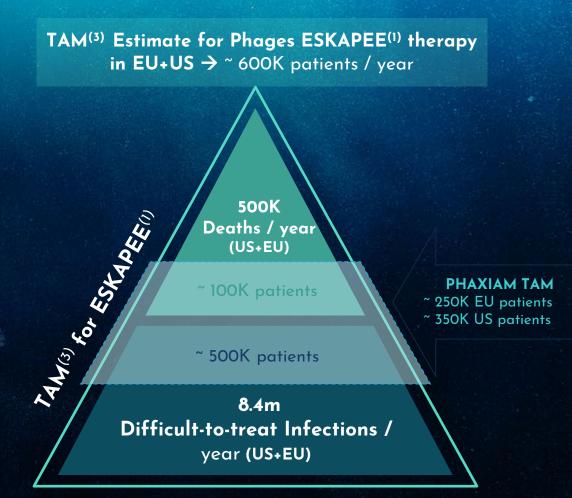
Pherecydes and Erytech merged to build PHAXIAM

Leveraging on Complementary Capabilities from both Executive Teams

# Phage Therapy: A Fast-emerging Large Targeted Addressable Market in EU / US

#### Significant Unmet Medical Needs

- Deaths from resistant bacterial infections reaching in 2024 ~ 500K patients in EU + US: ~200K (EU) and ~300K<sup>(4)</sup> (US) (Lancet<sup>(2)</sup>, sept 2024)
- Upwards of 8.4 million patients experience every year unresolved resistant bacterial / difficult-to-treat infections in high income countries: EU ~3.7m / US ~4.7m (Lancet<sup>(2)</sup>, sept 2024)
- Phage therapy applications will range from treating "difficult-to-treat" patients to "last-resort / death" patients → TAM<sup>(3)</sup> in EU and US ~ 600K patients



<sup>(1)</sup> ESKAPEE = most important pathogens covering ~70% of severe resistant infections: E. coli, S. aureus, K. Pneumonia, A. baumannii, P. aeruginosa, E. faecium, Enterobacter

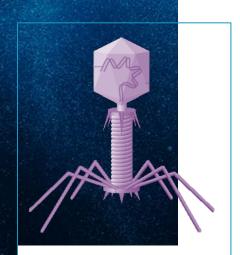


<sup>(2)</sup> Global burden of bacterial antimicrobial resistance 1990-2021: a systematic analysis with forecasts to 2050 (Lancet, Sept 2024)

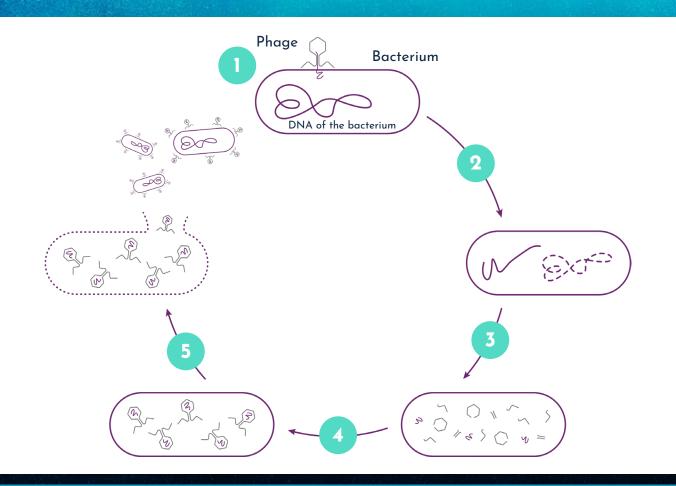
<sup>(3)</sup> Targeted Addressable Market

<sup>4)</sup> Estimated – internal estimation

### Phage Therapy, a Solution for Resistant Infections



Bacteriophages: viruses, natural predators of bacteria



#### Unique mode of action

- Specificity
- Speed (less than 45 min)
- Self-replication down to the last bacterium

Phage Therapy allows SIMPLE, EFFECTIVE and WELL-TOLERATED treatments

### The Strong Momentum of Phage Therapy

INCREASING IMPACT of difficult-to-treat resistant infections Rising concern among public authorities and medical community

High safety and promising clinical benefits from REAL-LIFE treatments Increased probability of success from early clinical evidence

Active collaboration with REGULATORY AGENCIES

Strong support / Clear development guidelines / Accelerated paths

GMP STANDARDIZATION & CMC developments Robust GMP processes / Well characterized phages

Better understanding of resistance mechanisms
NEW TOOLS to address potential emergence of phage resistance



CRITICAL NEEDS FOR ALTERNATIVE TECHNOLOGIES



PROMISING REAL-LIFE CLINICAL DATA



ATTRACTIVE REGULATORY CONTEXT



MATURITY
OF THE TECHNOLOGY



SOLUTIONS TO POTENTIAL RESISTANCE

Phage Therapy is a TOP-10 INNOVATION to be developed according to the 2023 World Economic Forum



# Leading Phage Therapy Platform

Leading Phage Therapy player in Clinical Development

Regular Interactions with Regulatory Agencies

Strong internal R&D, CMC & GMP Capabilities

**Proprietary PHAGOGRAM IVD Solution** 

Large Phage Bank for the most critical bacterial Infections

Strong IP with 87 patents filed



Developments within a regulatory framework validated by key health authorities







Network of prestigious scientific partners





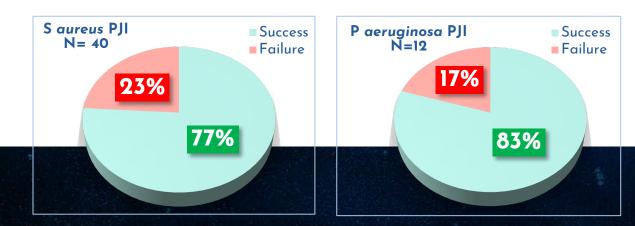


Leading shareholder in support of the sovereignty issue



### Real-life Clinical Data From ~130 Treated Patients

- STRONG SUPPORT from Regulatory Authorities & >15 hospitals
- SEVERAL ROUTES OF ADMINISTRATION TESTED, including local, intravenous, nebulisation, ...
- 7 DIFFERENT INDICATIONS TREATED with a majority of PJI



# PROMISING CLINICAL ACTIVITY RESULTS

(First 88 patients evaluated) 2020-2024

- EXCELLENT RESULTS observed in reported cases: safety + clinical benefit
- Several PUBLICATIONS

~80% CONTROL RATE of infection at 3 months for PJI Patients (n=52)

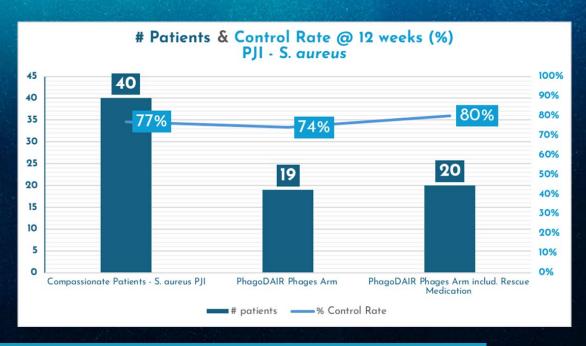
VERY PROMISING Data in « hard to treat » population

(very severe infections - 2<sup>nd</sup>/3<sup>rd</sup> line antibiotics)



# Results Of The PhagoDAIR I Pilot Study (In PJI) Very Consistent With Real Life Compassionate Data

- Design: non-comparative pilot study, including PJI Patients, recruited 29 patients, 26 of whom were evaluable for clinical activity
- Confirmation of the safety of PHAXIAM's anti-Staphylococcus aureus (S. aureus) phages
- Demonstration of an infection control rate of 74% (14/19)
- Overall rate of infection control, combining initial treatment and patients having a rescue medication after relapse, with 1 or 3 administrations injections, increased to 80% (16/20)



#### PHAXIAM Is Now Focusing On The GLORIA Phase II Study (estimated cost of €10m)

- which will enroll 100 patients in Europe and the United States from Q1 2025 onwards
- using expanded criteria compared with PhagoDAIR (Early & Late DAIR) → target population x7 larger
- which aims to provide robust proof-of-concept of the clinical benefit of its anti-S. aureus phages in PJI after 3
  injections of phages

### AAC\* Regulatory Status from French Health Authority (June 2022)



COMPASSIONATE
ACCESS
AUTHORIZATION
(AAC)
for anti-S. aureus phages

SOURCE OF REVENUES

To be extended to OTHER AAC\* INDICATIONS

Process towards an EARLY ACCESS AUTHORIZATION

To be extended to ORPHAN STATUS

An Important First Step For MARKET ACCESS In EUROPE

A New AAC (France) Is About To Be Filled Early February 2025



#### 3- Development Strategy

# Strong Demand From Physicians Opens A Complementary Market Access Business Model

- (1) PTMP = Pre-defined (standardized) finished product consisting of one or more bacteriophage strains
- (2) IPT = Phages Selected within a Preexisting GMP Phages portfolio based on Phagogram outcomes
- (3) AAC = Authorization for Compassionate Access → Compassionate Use (CU)
- (4) Market Authorization
- (5) Medicinal Product prepared in a Pharmacy in accordance with a medical prescription for an Individual Patient
- Critical medical needs
   No available
   registered product
- Phages positive reallife clinical data
- EMA concept paper

Standard
Medicinal Product
Development
(Directive 2001/83/EC)

-clinica

Drug Product (GMP)

# Clinical Phase II Phase III Compassionate Use (free of charge) AAC(3) in France (100% reimbursed)



Authorization

Phages Therapy
Medicinal
Products(1)

« PTMP »

Derogation Path without MA<sup>(4)</sup>

Named-patient Programs (NPP)

API Raw materials (GMP) Magistral Preparation<sup>(5)</sup>

GMP Phages Raw Materials (Vials)

Can be sold



Individualized
Phages
Treatment<sup>(2)</sup>
« IPT »

The Co-existence Of PTMP and IPT Regulatory Framework Mirrors Those Already Implemented in The Allergens Therapeutic Domain

3- Development Strategy

# PTMP and IPT Access Will Co-exist Concurrently In Various European Countries

PTMP

IPT

1- Phage Therapy Medicinal Product (PTMP<sup>(2)</sup>) Accelerated Regulatory Authorization 2- Individualized
Phages Therapy
(IPT(1))

Magistral preparation / Compounding

#### Consequently, PHAXIAM seeks to position itself to:

- 1. Capitalise on its first mover advantage in the strategically-important emerging IPT model, where market access can start as soon as 2026,
- 2. Leverage on its existing capabilities in PTMP to secure Conditional Marketing Approval (CMA) by H2 2027.





# PHAXIAM Has Strong Clinical Development and Market Access Capabilities in the PTMP<sup>(1)</sup> Model

Phages Therapy
Medicinal Product
(PTMP(1))

# 3 Main Pathogens Covered in Clinic

- S. aureus → PJI Pilot Trial, GLORIA PJI Phase II, Endocarditis Phase I PK, PhagoPIED Phase II (IST)
- P. aeruginosa → PyoPhaNeb Phase II POC (IST) - to be initiated
- E. coli → Phase I PK to be initiated



- Recent FDA IND clearance for GLORIA Phase II
- Large hospitals & KOLs network in EU/US, leveraging on ongoing clinical trials: PhagoDAIR (15 EU sites), GLORIA (35 EU sites + 10 US sites)
- PHAXIAM AAC<sup>(2)</sup> (Compassionate Use) Revenues to be extended to other indications

#### Clinical Strategy Value Drivers

- Relevant choice of Clinical indications (PJI) & clinical design to maximize Clinical POC for Phages
- Accelerated registration through CMA / Early Access in EU & US leveraging on Real-life compassionate clinical data
  - 1) Pre-defined (standardized) finished product consisting of one or more bacteriophage strains
  - (2) AAC = Authorization for Compassionate Access → Compassionate Use (CU)



### An Ambitious Clinical Development Strategy

### Target High-Value Indications

Severe Resistant Infections with High unmet medical needs high mortality rate / high budget impacts -> claims high prices

### Accelerate the Path to Global Registration

Launch the 1<sup>st</sup> global randomized Phase 2 study at international scale in PJI\* Leverage on potential Early access pathway (after Phase 2)

### **Diversify Portfolio**

Target several Life-Threatening Infections (Endocarditis, VAP\*\*, ...)
Target several Virulent & Resistant Bacteria (E. coli, P. aeruginosa, ...)



<sup>\*</sup> Prosthetic Joint Infections

<sup>\*\*</sup>Ventilated-acquired Pneumopathies

#### 3- Development Strategy

#### PTMP

# A Balanced Clinical Portfolio in High-Value Indications



GLORIA Enrolment Initiation Will Depend On Company's Future Non-dilutive Financial Resources, Currently Being Studied By The Company, And Will Be Scheduled Accordingly, Possibly Up To Q1 2026

### PJI, A Strategic Indication For PHAXIAM

- Relatively High incidence: ~50-60K PJI\* (US/EU5; 2027)
- Very High economic burden (cost ~ \$150K in US, €50-70K in EU)
- Most advanced player in EU and US (APT stopped, Armata 18 months behind)
- Clear leadership → 1st to Market

Attractive indication

Strong competitive position

PJI\* Strateai

Strategic indication

High unmet medical need

2

Highest probability of robust POC for Phages

- Rare & devastating complication
- 50% failure rate with DAIR\*\*
- High risk of re-infection (60%), amputation (~11%), mortality (25% at 5 years)
- Derisked by Real-life Compassionate experience
- Local route of administration

Unique and leadership position in the strategic PJI indication

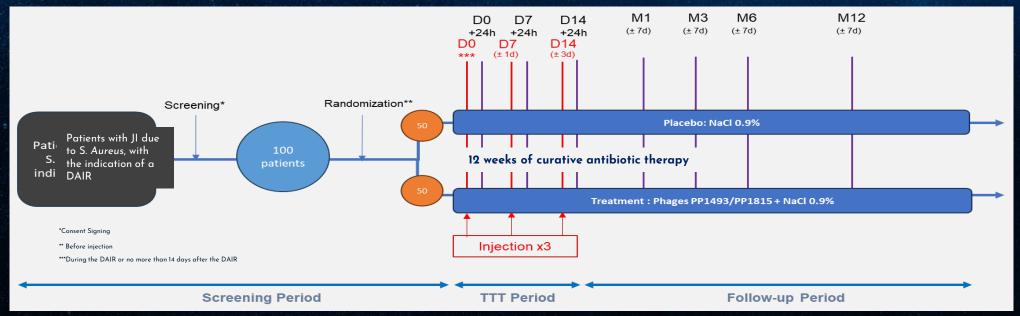
<sup>\*\*</sup> SOC = Debridement, Antibiotic, Implant Retention



# GLORIA–first global Phase 2 POC\* clinical study of phages in PJI

A randomized, comparative, double-blind, clinical study to evaluate the efficacy and safety of phage therapy in patients with osteoarticular knee or hip infection (PJI) due to Staphylococcus aureus, with the indication of DAIR (including early & late DAIR patients)

**Study primary objective**: assess the safety and efficacy (% of patients with clinical cure at M3) of phage therapy + DAIR compared with placebo + DAIR up to 3 months





# Preparation of the GLORIA Study

- Positive and consistent feedback from the FDA (pre-IND meeting) and EMA (scientific advice)
- Regulatory filings → Approval obtained from FDA in Q4 2024, expected from EMA and MRHA in Q1 2025
- Sites selection ongoing: ~45 sites and countries (FR, ESP, GER, NLD, ITA, UK, US)
- Launch of the clinical study up to Q1 2026, clinical results expected in Q3 2027

- Progress in line with our objectives
- GLORIA is our most important asset, having the highest priority



# Near Term Commercial Opportunities Arise From the Emergence of the Individualized Phages Therapy (IPT<sup>(1)</sup>) Market Access Model

**IPT** 

# Strong Demand from Physicians



 High unsatisfied clinical needs → new solutions to address morbidity / mortality induced by severe resistant infections, when the PTMP<sup>(2)</sup> model cannot address clinical needs, as no Medical Products are available

• **Promising clinical evidence** from hundreds of successful compassionate treatments in key reference hospitals across EU

#### **EMA Concept paper Guidelines**

- → Regulatory landscape evolving, making a special case on bacteriophages "Named-Patient Use Program" (NPP)
- Phages Therapy Medicinal Product: predefined (standardised) finished product consisting of one or more bacteriophage strains > Major requirements for wellconducted RCTs
- Individualized Phages Therapy (IPT) → Delineate context of clinical use where Medical Products cannot be used / are not available

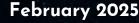
# Individualized Phages Therapy (IPT)

- Magistral Preparation / Compounding with <u>GMP</u> Phages
- Pre-requisite for Regulatory
   Validation per country
- (e.g. Exemption granted in Belgium)
- Based on a Diagnostic Test (Phagogram CE marked)
- Selection of Phages drawn from a pre-existing GMP Phages portfolio

(2) Pre-defined (standardized) finished product consisting of one or more bacteriophage strains

«Push» from Regulatory Stakeholders (EMA) & National Bodies







<sup>(1)</sup> IPT model = Phages Selected within a Pre-existing GMP Phages portfolio based on Phagogram outcomes



# PHAXIAM Has Very Recently Disclosed A Strategic Alliance

### With TECHNOPHAGE In IPT



PRESS RELEASE

- Combined 25 GMP Phages to cover by end 2025 five of the most critical pathogens (S. aureus, P. aeruginosa, E. coli, K. pneumoniae, A. baumannii) and expanded by the end 2026 to 35-45 GMP Phages and 2 additional pathogens
- To provide physicians across Europe with a comprehensive GMP phage portfolio and a diagnostic solution allowing the implementation of Individualized Phages Therapies (IPT)
- Collaboration on the GMP Phages manufacturing and diagnostic capabilities development
- Concurrently both parties continue to independently develop their classical clinical Phages Therapy Medicinal Product (PTMP) pathway

PHAXIAM Therapeutics and Technophage Enter Strategic Collaboration On Individualized GMP Phages Therapies (IPT) Against Bacteria Responsible For ~ 70%<sup>(1)</sup> Of The Most Common Severe Resistant Infections

- Combined 25 GMP<sup>(2)</sup> Phages Portfolio to cover by end 2025 five of the most critical pathogens (S. aureus, P. aeruginosa, E. coli, K. pneumoniae, A. baumannii) and expansion by end 2026 to 35-45 GMP Phages and two additional pathogens
- Opportunity to provide physicians with access to a comprehensive GMP phage portfolio and a diagnostic solution enabling the implementation of Individualized Phages Therapies (IPT)
- Collaboration on the GMP Phages manufacturing and Phages-Susceptibility-Testing (PST) capabilities development
- Concurrently both parties continue to independently develop their traditional clinical Phages Therapy Medicinal Product (PTMP) pathway

Lyon (France) / Lisbon (Portugal), January 30, 2025 – 06:00 pm CET - PHAXIAM Therapeutics (Euronext: PHXM - FR0011471135), a biopharmaceutical company ("PHAXIAM" or "the Company") developing innovative treatments for severe and resistant bacterial infections and Technophage SA ("Technophage"), a Portuguese company specializing in GMP phage development, today announces a strategic collaboration. This strategic partnership aims to provide physicians across Europe with access to a comprehensive GMP phages portfolio, enabling the implementation of IPT through shared capabilities.

This collaboration seeks to deliver a faster and more effective response to the growing challenge of antimicrobial-resistant infections. By combining PHAXIAM's GMP phages portfolio and advanced diagnostic capabilities, including its phagogram-based approach, with Technophage's complementary GMP phages portfolio and GMP manufacturing expertise, the partnership aims to drive innovation and accelerate access to IPT in Europe.

Expanding the GMP Phage Portfolio to Advance Individualized Phages Therapies (IPT)

The combined GMP phage portfolios will significantly enhance the number and diversity of GMP phages available for IPT. The partnership aims to achieve a collection of 25 GMP phages by the end of 2025 and 35-45 GMP phages by the end of 2026. This expanded portfolio will target at least 7 of the most critical pathogens: S. aureus, P. aeruginosa, E. coli, K. pneumoniae, A. baumannii, in addition to two other key pathogens. Together, these seven pathogens account for approximately 70%(1) of the most prevalent and difficult-to-treat antimicrobial-resistant infections.

Shared manufacturing and phagogram capabilities

PHAXIAM and Technophage will collaborate on GMP phages manufacturing and supply through the following arrangements:

This Partnership Further Supports PHAXIAM IPT Model While Strengthening Our Leadership Position In The Growing Phages Therapy Market



# PHAXIAM's Priority Targets: EU Countries Familiar with Compounding Pharmacies delivering Magistral Preparations to Physicians

#### UK

- Strong interest from Physicians for Phages

  Magistral preparation concept / Compounding very
  much developed
- Regulatory constraint today → to be discussed and validated by MHRA for general use Solution funded by national / regional / hospital envelops

#### FRANCE

Strong interest from Physicians for Phages
Magistral preparations less used than before /
reduced number of compounding organisations, but
increasing again due to pharma products shortages
AAC process in place as Compassionate Use

#### SPAIN

Strong interest from Physicians for Phages
Magistral preparations progressively
disappeared / not a common practice

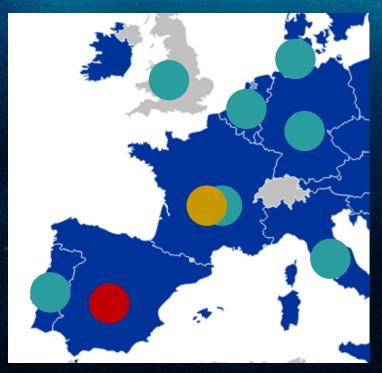
#### **PORTUGAL**

Physicians want to use Phages Magistral preparation recently approved for Phages

#### NORDIC

Strong interest from Physicians for Phages

Magistral preparation / Compounding common practice



#### BELGIUM

- Strong interest from Physicians for Phages
- Magistral preparation common practice benefiting from an exemption

#### **NETHERLANDS**

Strong interest from Physicians for Phages
Magistral preparation / Compounding developed

#### **GERMANY**

Strong interest from Physicians for Phages
Magistral preparation/compounding feasible
and standard practices

#### ITALY

Physicians want to use Phages
Magistral preparation commonly used / large
compounding community existing

Increasing Interest From Physicians For GMP Phages All Over Europe Magistral Preparation / Compounding Are Common Practices Particularly In Northern Europe

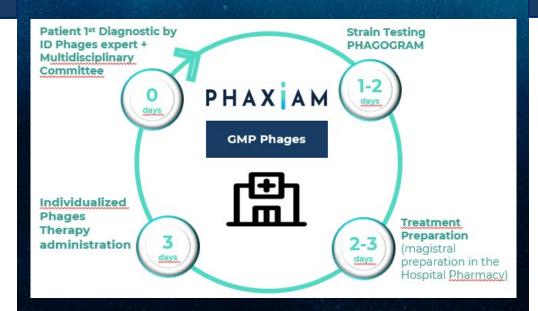


 Pre-defined (standardized) finished product consisting of one or more bacteriophage strains

# PHAXIAM Will Deliver IPT to Patients in Key Reference Hospitals As Soon As 2026

#### **Actions Plan**

- Obtain Local regulatory approval (national / regional) for magistral preparation (leveraging on existing exemption)
- Develop the EU network within reference hospitals (physicians, pharmacists) to be extended to smaller hospitals
- Set-up locally Supply chain and Diagnostic capabilities → Phagogram to be transfered



#### **Value Drivers**

- Average Selling Price of ~€20-25K (EU)
- Treatment invoiced at a local/hospital level, Regional level in some countries
- HTA/Payor negotiation in a 2nd step leveraging on KOL's concerted efforts to support creation of reimbursement codes, at local / national levels

# Emerging Paneuropean Specialty Pharma in Critical Care Targeting Positive FCF<sup>(1)</sup> AND Profitability From 2027

**PTMP** 

**IPT** 

Paneuropean Specialty Pharma in Critical Care

#### Individualized Phages Therapy (IPT)

- TAM in EU/US ~600K patients, of which ~250 K patients in EU
- A Fast-emerging Large Market of > ~€10bn (EU+US)
- Conservative Average Selling Price of ~€20-25K
   (EU)
- Not subject to any clinical development risk
- EU market access Scale-up to reach
  - ~1K pts / 30 hospitals in 2027; Potential Sales →
     €20m
  - ~7-8K pts / 100 hospitals in 2030; Potential Sales
     → ~€150m
- Conservative 2030 Commercial Target is limited to ~3% of TAM

Fully integrated platform including R&D, GMP manufacturing

Strong relationships with KOLs & Physicians

Presence in major reference hospitals in EU

Strong relationships with Regulatory authorities across EU / US

Diagnostic robust solution in place & potential future reference method

Market Access capabilities

Phage Therapy Medicinal Product (PTMP)

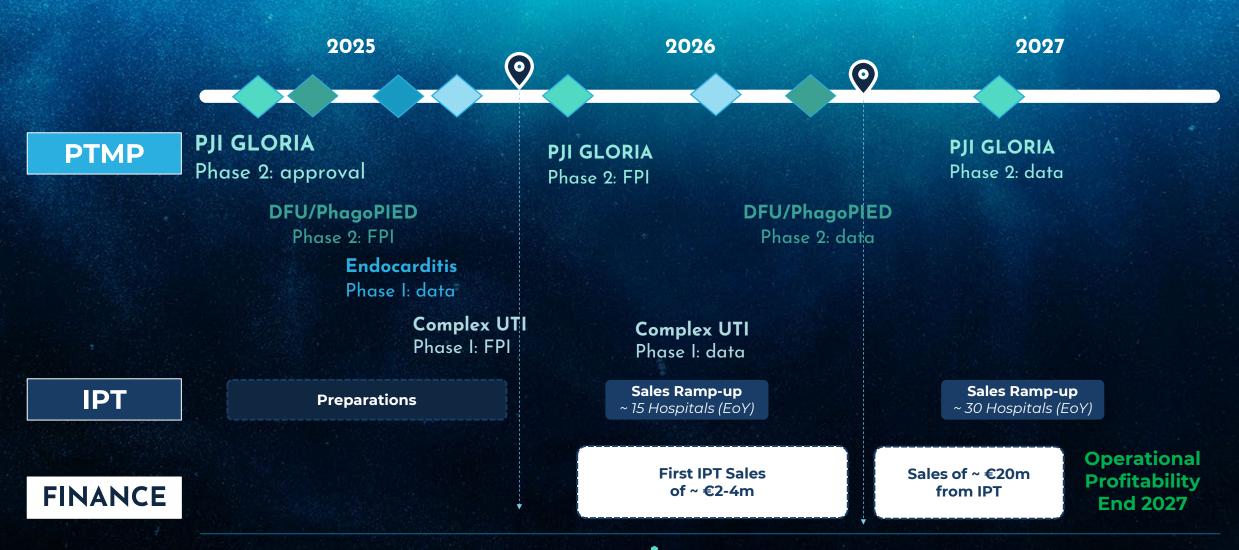
- AAC (Compassionate Use) Potential Sales → ~
   €4m in 2027 (PJI + other indications)
- PJI (lead clinical indication)
  - TAM(1) in EU/US ~ 40K pts / year
  - Average Selling Price of ~ €20-25K (EU) and ~ €25-30K (US)
  - Seeking Conditional Market Approval (CMA)
     / Early access pathways in H2 2027
  - PJI CMA Potential Sales → ~ €8m in 2028;
     €90-100m in 2031

PHAXIAM'S Market Access Strategy Is To Rely On Two Concurrent Commercial Pillars: IPT (magistral preparation) and PTMP (ACC + PJI CAM)



#### 4- Communication & Financing

### **Expected Major Short Term Clinical Catalysts**







### Financial Position & Objectives

- Major shareholders (equity share): BPI (25%), Auriga / Elaia (8%), Go Capital (5%)
- Listed @Euronext: valuation of €18m
- Capital increase of €7.8m in June 2024
- Cash Runway into March 2025
- Financing
  - Non-dilutive funding (EU, France, Region)
  - Dilutive funding: Private placement in January 2025, targeting €15m; use of proceeds: GLORIA study conduct (1st global EU/US study in PJI\* and Phage therapy) + other clinical studies

Till The Market PHAXIAM Still Needs €15-20m To Be Raised In Equity



# PHAXIAM, An Emerging Specialty Pharma In Critical Care

PTMP

IPT

- Millions of patients experience every year unresolved resistant bacterial/ difficult-to-treat infections.
- Facing this critical medical need, there is strong demand from KOLs /Physicians for Phages therapy.
- Concurrently with its classical clinical development pathway (Phages Therapy Medical Product=PTMP), EMA has
  opened the market for the commercialization of Individualized Phages Therapy (IPT) magistral preparations.
- PTMP and IPT Models are complementary and synergistic approaches that can be managed by PHAXIAM with limited additional resources.
- PHAXIAM will benefits greatly from these two complementary commercial pillars:
  - IPT with very large potential that will secure short term revenues (2026-2030),
  - PTMP with already existing AAC Revenues, then potential conditional market approval (CMA) from H2 2027.
- PTMP and IPT form together a self-reinforcing virtuous cycle for Phages therapy:
  - Commercial success in IPT will help finance PTMP programs and facilitate rapid uptake of future approved medicinal products,
  - Success (clinical validation) in PTMP will help broaden clinical and market acceptance of IPT in areas not yet addressable by PTMP.
  - This is strategically important because PHAXIAM is the only competitor with the capabilities to succeed in both markets

PHAXIAM targets positive Free Cash Flow and Profitability from 2027



# Thanks PHAX AM

# Key Technology Assets for PHAXIAM Treatments

- 1 SELECT phages to maximize breadth of repertoire Internal PHAXIAM Technology and Expertise
- PRODUCE large scale GMP batches of high purity
  Internal PHAXIAM process development Capabilities and Expertise
  Industrial partnership to produce "off-the-shelf" GMP-grade phages
- TEST PHAGOGRAM for a precision therapy PHAXIAM proprietary IVD Test
- 4 DISTRIBUTE personalized therapeutics to patients' bed Supply chain in place with a few days leadtime









Discovery, Screening, Characterization, GMP production, Testing, Distributing

# Manufacturing & Logistics strategic capabilities

In-house process development & analytical science

In-house highly purified phages manufacturing

Strategic partnership with MB Pharma (CMO, EU) to manufacture GMP bacteriophages clinical batches

Pharmaceutical supply chain mastered to ensure robust and short lead time clinical supply (clinical studies, AAC, ....)

#### Major achievements





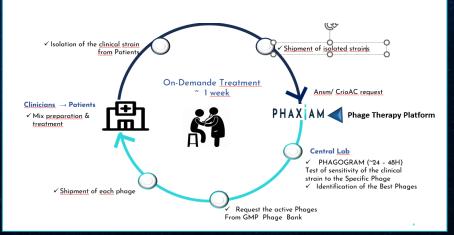








- > 35 GMP clinical batches produced
- Low Manufacturing COGS
- Available capacity till early market launch
- Short supply lead time (> 1 week)



Manufacturing & Logistics Capacities Fit to Address future Clinical Demand

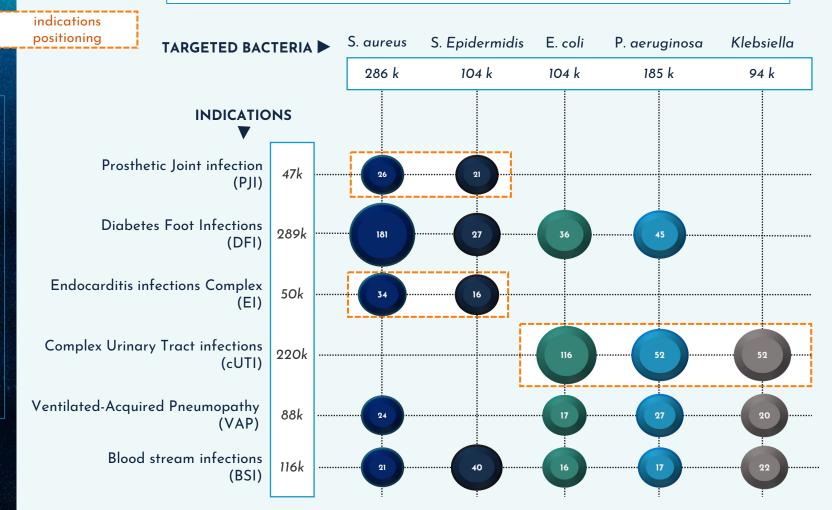
# Targeting High-value Resistant Infections

Estimated population 2027 (incidence in US & EU5)

Life-Threatening Conditions

Potential Orphan Status Indications

The most severe Hospital-Acquired and Resistant Infections



February 2025



# Additional Clinical Studies

TRIALS	STATUS AND PROGRESS
Endocarditis Infections (EI) S. aureus Phase I PK	<ul> <li>Demonstration for IV indications before Registration Study</li> <li>Resistant infections in cardiac chambers and valves</li> <li>IV-administered Phages</li> <li>Key milestones : First Patient-In, April 2024</li> </ul>
Complex Urinary Tract Infections (cUTI) E. coli Phase I PK	<ul> <li>Demonstration for intra-bladder administration before Registration Study</li> <li>cUTI with resistant E. Coli infections in the bladder</li> <li>Phages administered locally into the bladder</li> <li>Key milestones : ANSM study validation in April 2024</li> </ul>