
PHAXIAM

PHAXIAM

Building a Global Leader in Severe Infections Therapies

January 2025

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

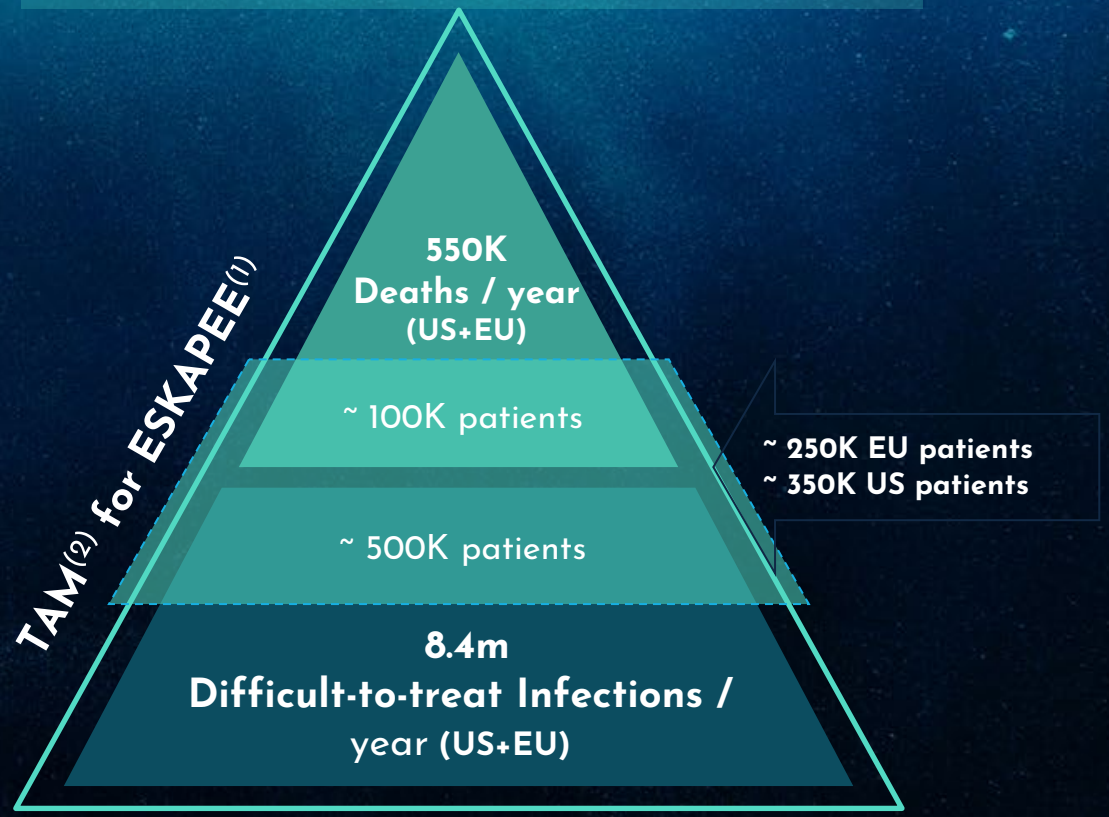
Leveraging on Complementary Capabilities from both Executive Teams

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

Significant Unmet Medical Needs

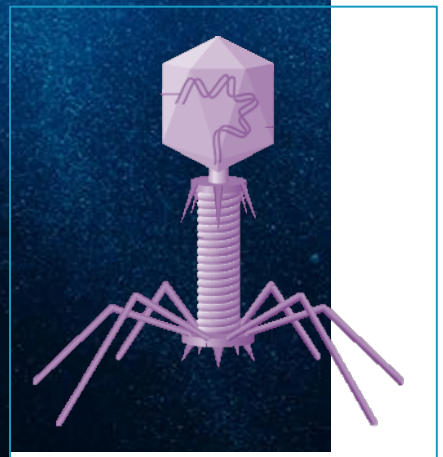
- **Deaths from resistant bacterial INFECTIONS reaching in 2024 ~ 550K patients in EU + US:** ~250K (EU) and ~300K[4] (US) (Lancet[2], sept 2024)
- **Upwards of 8.4 million patients experience every year unresolved resistant bacterial/ difficult-to-treat INFECTIONS in high income countries:** EU ~3.7m / US ~4.7m (Lancet[2], sept 2024)
- **Phages therapy applications will range from treating "difficult-to-treat" patients to "last-resort / death" patients → TAM[2] in EU and US** ~ 600K patients

TAM[2] Estimate for Phages ESKAPEE[1] therapy in EU+US → ~ 600K patients / year

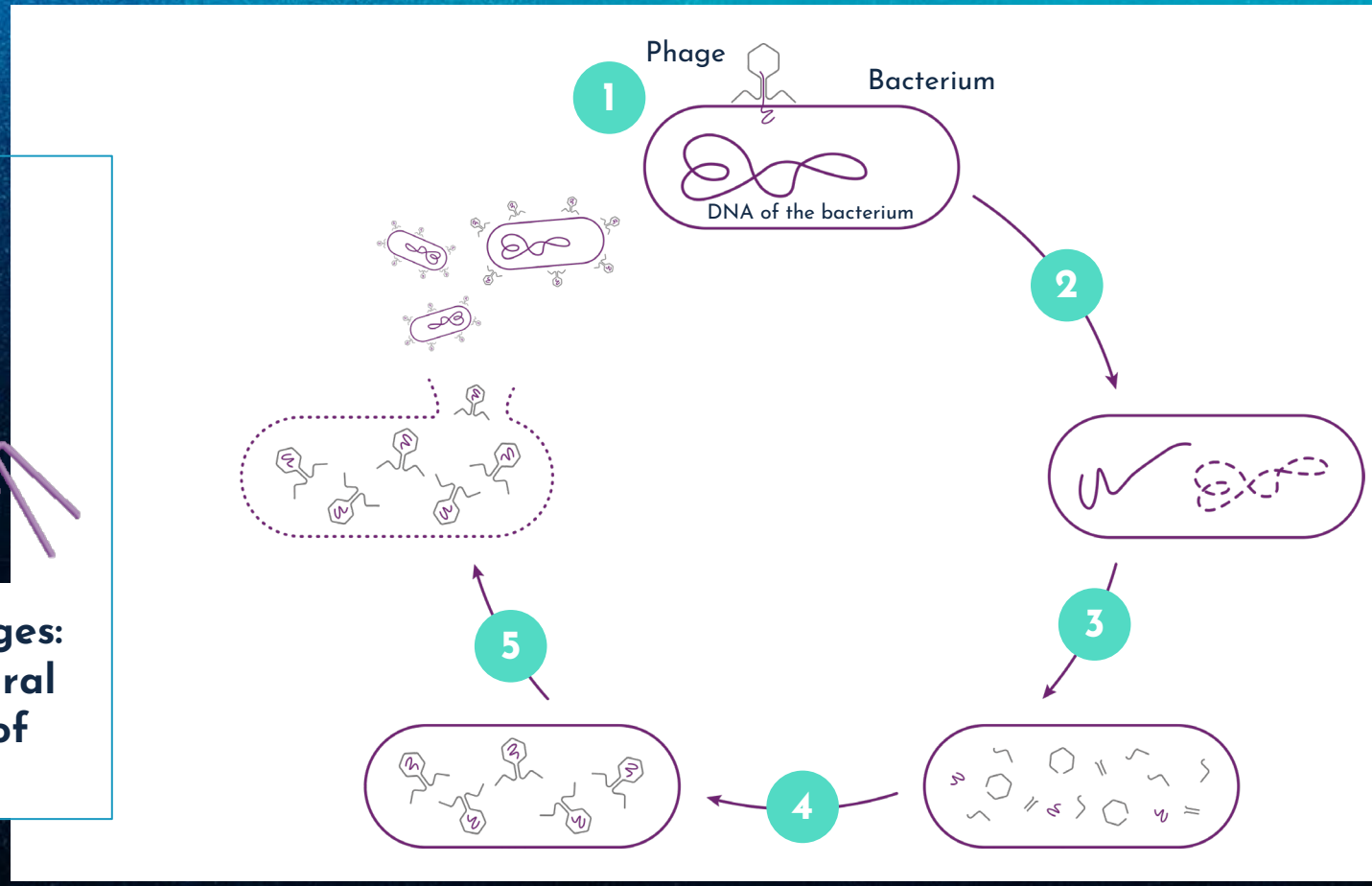


(1) ESKAPEE = most important pathogens covering ~90% of severe resistant infections: E. coli, S. aureus, K. Pneumonia, A. baumannii, P. aeruginosa, E. faecium, Enterobacter
(2) Global burden of bacterial antimicrobial resistance 1990–2021: a systematic analysis with forecasts to 2050 (Lancet, Sept 2024)
(3) Targeted Addressable Market
(4) 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	→ CRITICAL NEEDS FOR ALTERNATIVE TECHNOLOGIES
High safety and promising clinical benefits from REAL-LIFE treatments Increased probability of success from early clinical evidence	→ PROMISING REAL-LIFE CLINICAL DATA
Active collaboration with REGULATORY AGENCIES Strong support / Clear development guidelines / Accelerated paths	→ ATTRACTIVE REGULATORY CONTEXT
GMP STANDARDIZATION & CMC developments Robust GMP processes / Well characterized phages	→ MATURITY OF THE TECHNOLOGY
Better understanding of resistance mechanisms NEW TOOLS to address potential emergence of phage resistance	→ 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 Edge 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

PHAXIAM

Developments within a regulatory framework validated by key health authorities

ansm

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FDA
U.S Food and Drug Administration

Network of prestigious scientific partners

Institut Pasteur

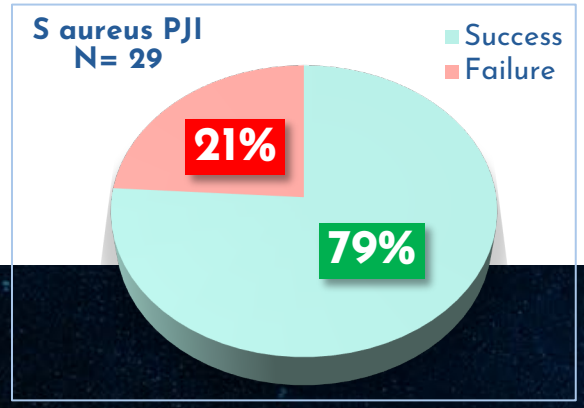
Crioac GSO

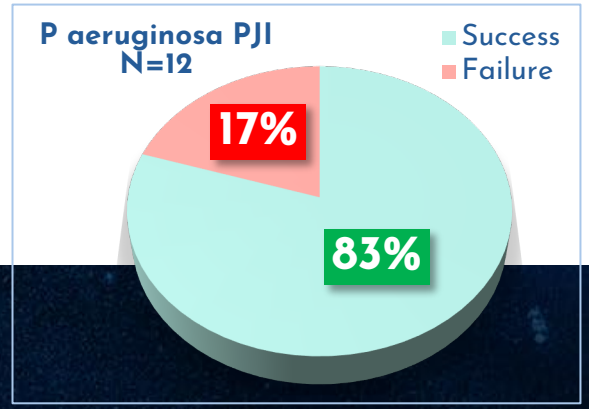
INRA
SCIENCE & IMPACT

BIOASTER
MICROBIOLOGY TECHNOLOGY INSTITUTE

Real-life Clinical Data From ~120 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 77 patients evaluated)
2020-2024

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

~ 80% CONTROL RATE of infection @3months for PJI Patients (n=41)

VERY PROMISING Data in « hard to treat » population

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

AAC* Regulatory Status from French Authority (June 2022)

ansm
Agence nationale de sécurité du médicament et des produits de santé

COMPASSIONATE ACCESS AUTHORIZATION (AAC)

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

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 Pre-existing 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

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

Drug Product (GMP)

Pre-clinical

Clinical

Phase I

Phase II

Phase III

Compassionate Use
(free of charge)
AAC(3) in France (100% reimbursed)

Market Authorization
Can be sold

Phages Therapy Medicinal Products(1)
« PTMP »

- *Critical medical needs + No available registered product*
- *Phages positive real-life clinical data*
- *EMA concept paper*

Derogation Path without MA(4)

Named-patient Programs (NPP)

API
Raw materials (GMP)

Magistral Preparation(5)

GMP Phages Raw Materials (Vials)
Can be sold

Individualized Phages Treatment(2)
« IPT »

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

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

PTMP
IPT

1- Phage Therapy Medicinal Product (PTMP[2])

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.

(1) IPT model = Phages Selected within a Pre-existing GMP Phages portfolio based on Phagogram outcomes
(2) PTMP model = Pre-defined (standardized) finished product consisting of one or more bacteriophage strains

PTMP

PHAXIAM Has Strong Clinical Development and Market Access Capabilities in the PTMP(1) Model

Phages Therapy Medicinal Product (PTMP(1))

- **Strong push from FDA / EMA** to seek robust clinical POC in RCTs + Based on a EU Pharmacopeia monograph (March 24)
- **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(2)** (Compassionate Use) **Revenues to be extended to other indications**

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

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)**

PTMP

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 1st 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**, …)

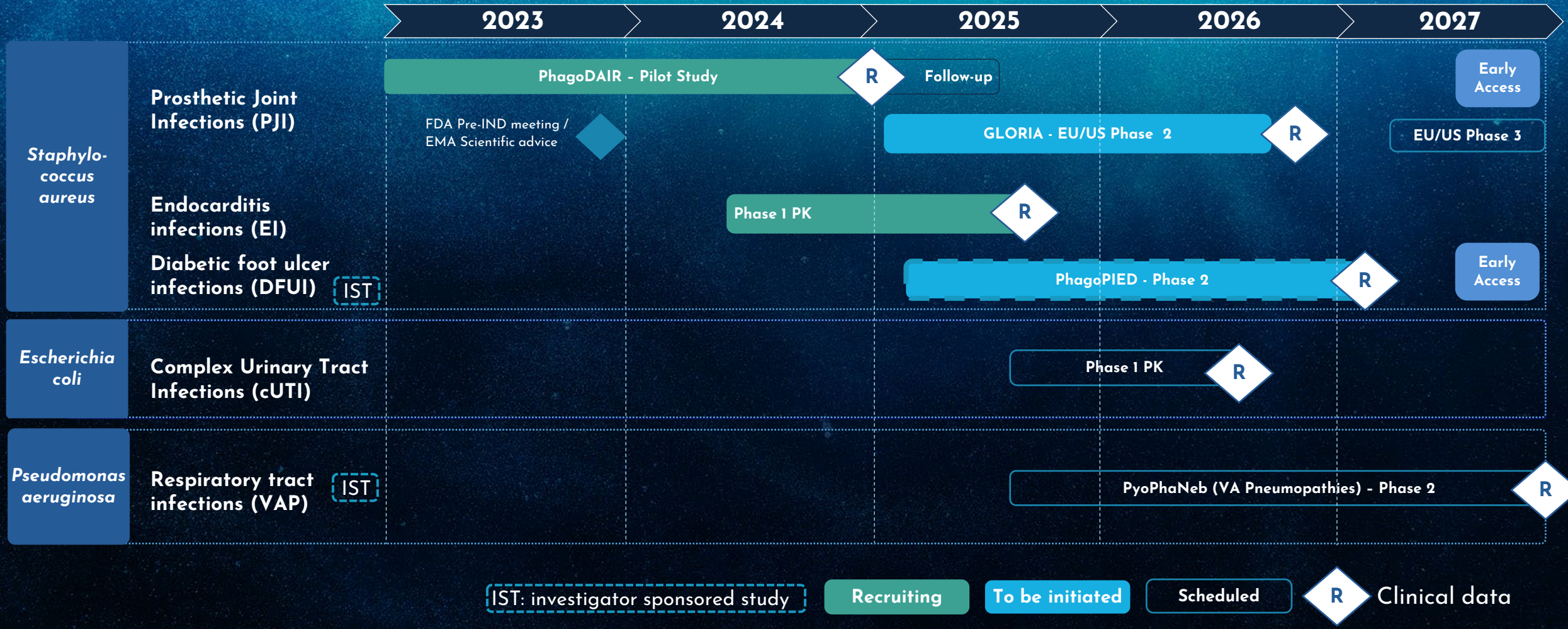
Target several Virulent & Resistant Bacteria (E. *coli*, P. *aeruginosa*, …)

* Prosthetic Joint Infections

**Ventilated-acquired Pneumopathies

A Balanced Clinical Portfolio

PTMP



January 2025

PHAXIAM

PTMP

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

PJI* Strategic indication

1. **Attractive indication**
2. **High unmet medical need**
3. **Strong competitive position**
4. **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

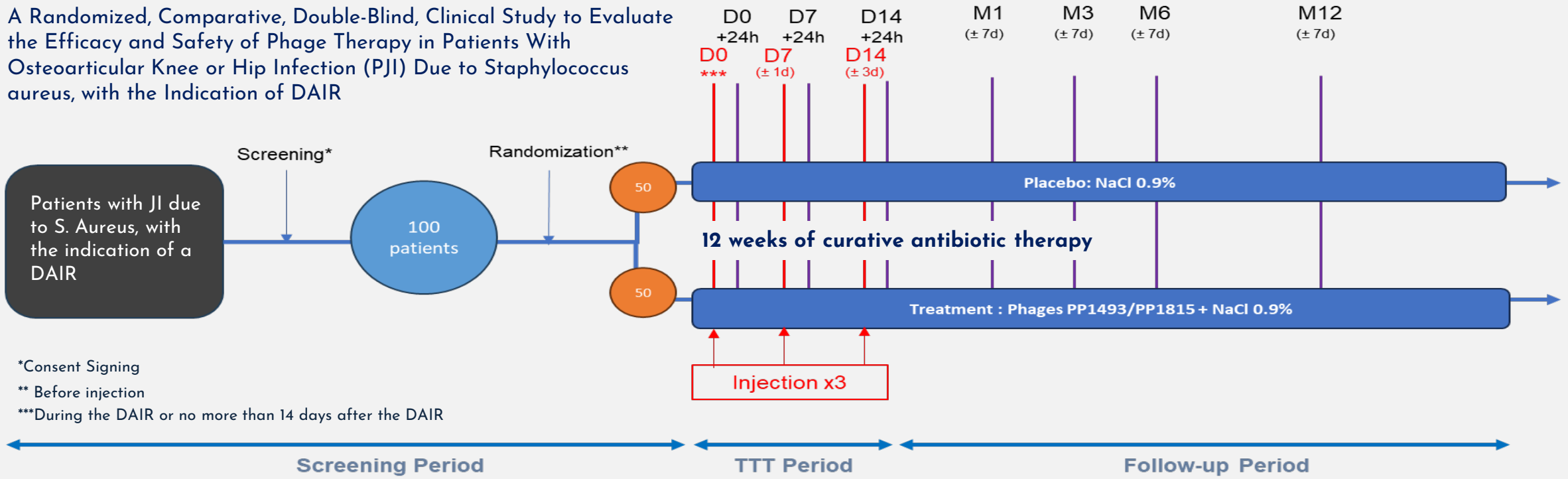
PHAXIAM

** Prosthetic Joint Infection (PJI)*
*** SOC = Debridement, Antibiotic, Implant Retention*

PTMP

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



- Primary endpoint: Safety; Efficacy (% of patients with clinical cure at M3)
- The GLORIA study is the most strategic clinical trial for PHAXIAM

PTMP

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 202, expected from EMA and MRHA in early Q1 2025
- Sites selection ongoing: ~45 sites and countries (FR, ESP, GER, NLD, ITA, UK, US)
- Launch of the clinical study in Q1 2025, clinical results expected in Q3 2026

- Progress in line with our objectives
- GLORIA Is Our Most Important Asset, Having The Highest Priority

PTMP

Expected Major Short term Clinical Catalysts

Near Term Commercial Opportunities Arise From the Emergence of the Individualized Phages Therapy (IPT[1]) 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[2] 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

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

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 well-conducted 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 GMP 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**

(1) IPT model = Phages Selected within a Pre-existing GMP Phages portfolio based on Phagogram outcomes
(2) Pre-defined (standardized) finished product consisting of one or more bacteriophage strains

For IPT[(1)], PHAXIAM Is Targeting As A 1st Priority European Countries Familiar with Magistral Preparation

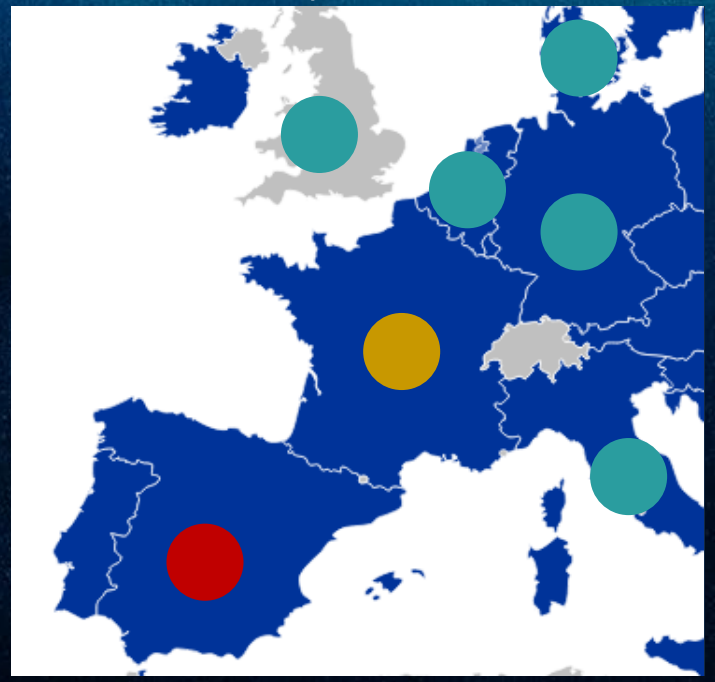
IPT

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
- AAC process in place as Compassionate Use

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

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 Phages All Over Europe
Magistral Preparation / Compounding Are Common Practices In Northern Europe

PHAXIAM

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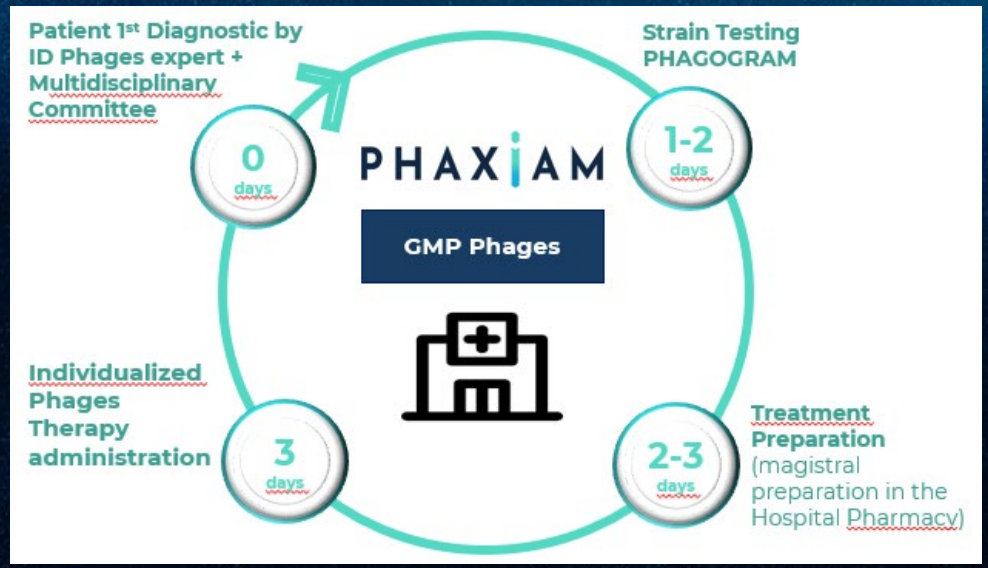
PHAXIAM Will Deliver IPT to Patients in Key Reference Hospitals As Soon As 2026

IPT

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

PTMP And IPT Models Are Synergistic Market Channels With Largely Overlapping Requirements

PTMP
IPT

Paneuropean Specialty Pharma in Critical Care

Individualized Phages Therapy (IPT)

- TAM(1) 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(1)

- 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 2027; €90-100m in 2030**

Synergies Are Reducing The Investments Requirements To Scale-up The IPT Model

Emerging Paneuropean Specialty Pharma in Critical Care Targeting Positive FCF(1) AND Profitability From 2027

PTMP

IPT

Paneuropean Specialty Pharma in Critical Care

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

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

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

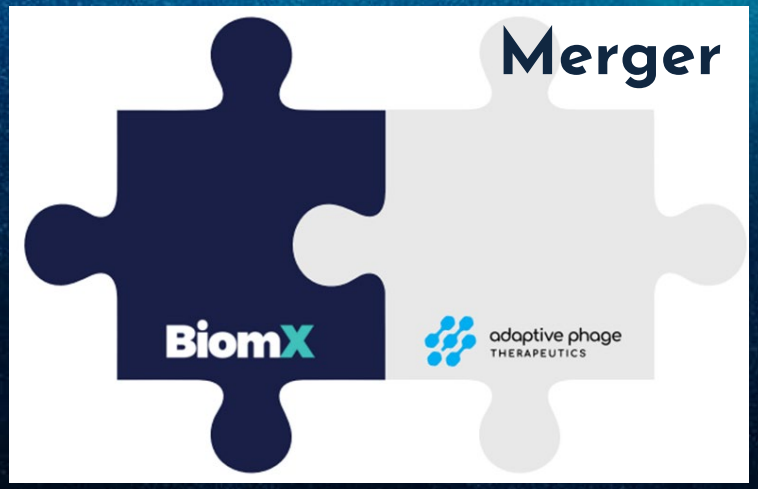
*Prosthetic Joint Infections

Thanks | PHAXIAM

Reinforced interest in Phage Therapy

Major Commitment from Top Tier US investors in March 2024

Merger



Purchase agreement with a $50m financing led by Top tier investor base, incl. Deerfield and Orbimed

Financing

ARMATA PHARMACEUTICALS
PURPOSEFUL • PRECISE • POWERFUL

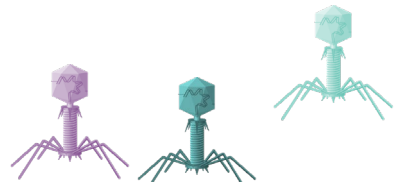
INNOVIVA

Armata Pharmaceuticals has recently announced a $35m refinancing with Innoviva

Growing attractiveness of the phage-therapy field to leading investors

Key Technology Assets for PHAXIAM Treatments

1 **SELECT phages to maximize breadth of repertoire**
Internal PHAXIAM Technology and Expertise



2 **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

3 **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

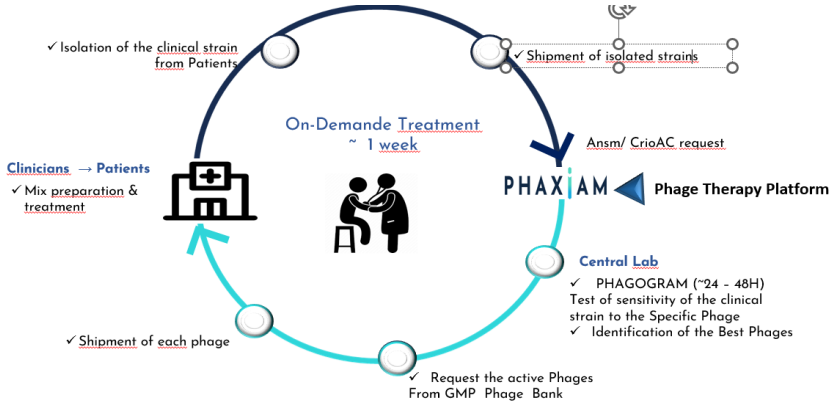
In-house highly purified phages manufacturing

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)



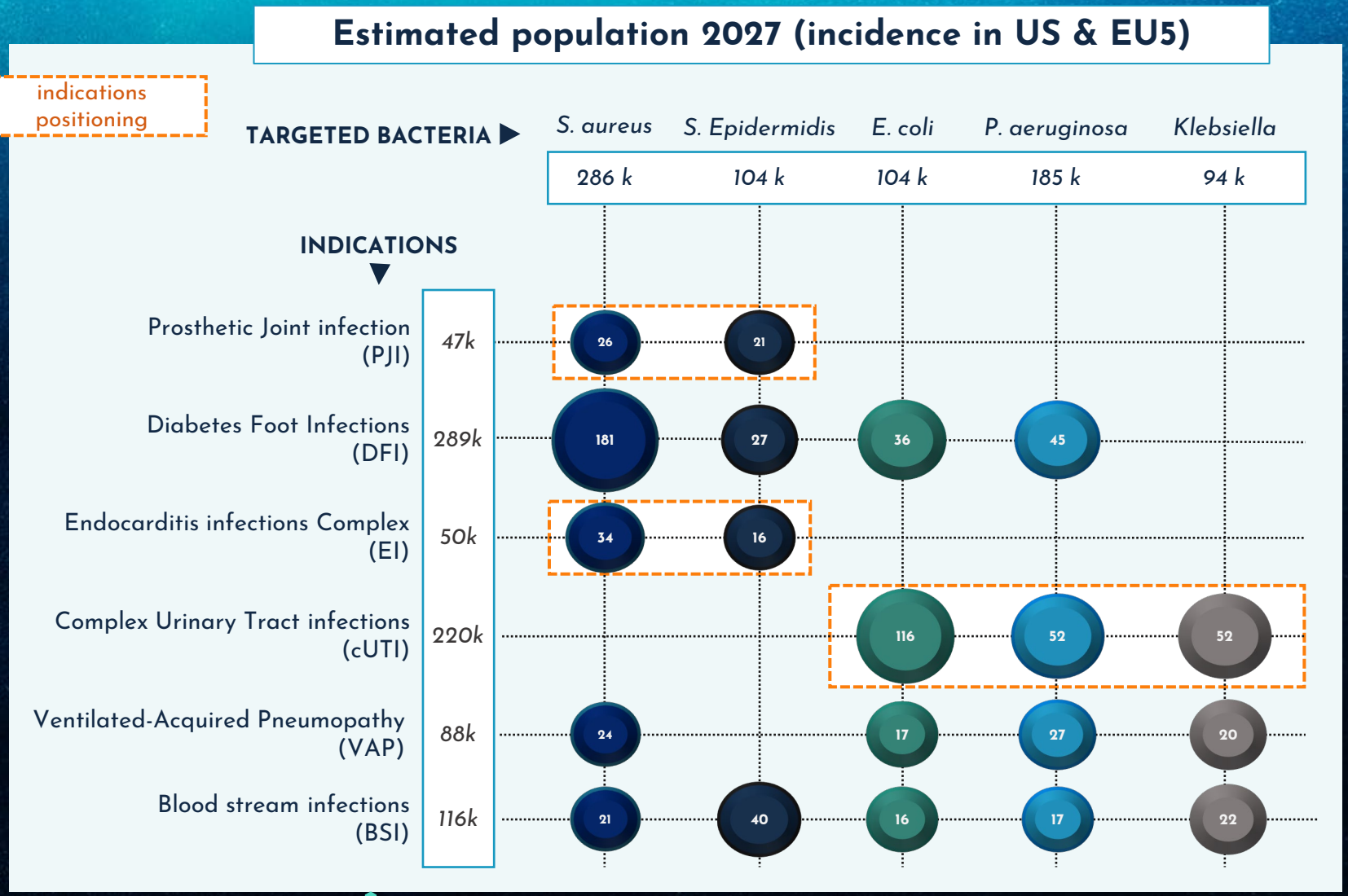
Manufacturing & Logistics Capacities Fit to Address future Clinical Demand

Targeting High-value Resistant Infections

Life-Threatening Conditions

Potential Orphan Status Indications

The most severe Hospital-Acquired and Resistant Infections



Additional Clinical Studies

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