PHAXIAM

Building a Global Phages Therapy Leader

"Evolving Strategic Context for Phages, Introducing New Opportunities"

Webinar – November 27, 2024

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November 2024

Agenda

01 **PRESENTATION – "Evolving Strategic Context for Phages, Introducing New Opportunities"**
(T. du Fayet, PHAXIAM CEO & P. Birman, PHAXIAM CMO; 30')

02 **ROUND TABLE – "Critical Need for Individualized Phages Treatments in Europe"**
(Experts panel; 40')

03 **QUESTIONS & ANSWERS** (All; 15')

04 **CONCLUSION** (T. du Fayet, PHAXIAM CEO; 5')

Thibaut du Fayet
CEO

Pascal Birman
CMO

Jérôme Bailly
CTO

PHAXIAM

Four Major Strategic Topics To Be Addressed

(1) Major Regulatory changes are occurring and impacting the Phages therapy Landscape

(2) In 2025, PHAXIAM will initiate a new positioning in a complementary Market Chanel to Medicinal Products, in order to generate shorter term revenues

(3) PHAXIAM maintains its ambition to obtain a Conditional Market Approval for its phages upon completion of the GLORIA trial in 2027

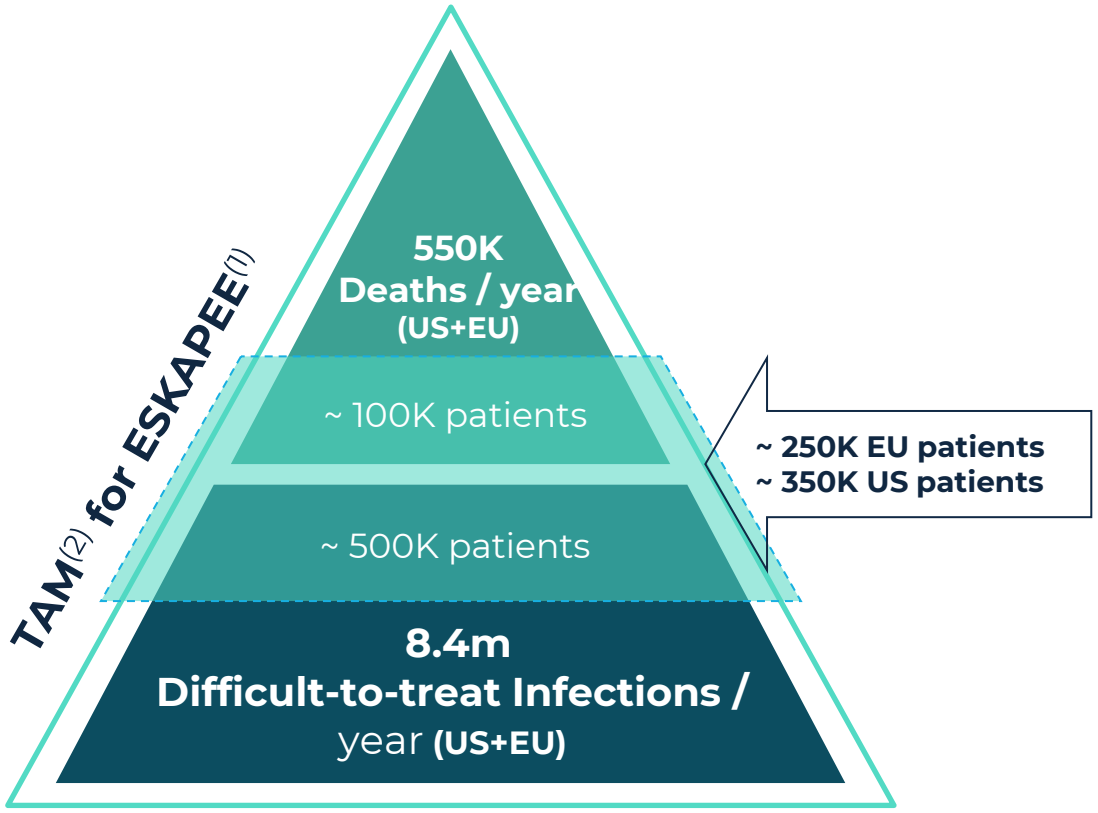
(4) Based on these developments, PHAXIAM could reach operating profitability and positive Free cash flow in 2027

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

Significant Unmet Medical Needs

- **Deaths from resistant bacterial INFECTIONS in 2024 reaching ~ 550K patients in EU + US:** ~250K (EU) and ~300K[3] (US) (Lancet[4], 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[4], 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) Targeted Addressable Market
(3) Estimated – internal estimation
(4) Global burden of bacterial antimicrobial resistance 1990–2021: a systematic analysis with forecasts to 2050 (Lancet, Sept 2024)

PHAXIAM, Global Phages Therapy Leader

- Large Phages portfolio for the most critical bacterial Infections (coverage ~70% severe infections)
- Leading Edge in Clinical Development (PJI global Phase 2 POC)
- Promising & derisking clinical Data in « hard to treat » population (> 120 patients treated in real life compassionate use)
- Strong relationships with European and US Phages KOLs
- Regular Interactions with Regulatory authorities in EU and the US (EMA, FDA, ANSM, PEI, MHRA, …)
- Robust internal R&D, CMC & GMP Manufacturing Capabilities
- Proprietary PHAGOGRAM IVD Solution (CE marked)
- Strong IP with 87 patents filed

1

Developing Phages Therapy within a regulatory framework validated by FDA and EMA

2

Clinical Developments involving the most prominent KOLs & Hospitals in EU

3

Research Network of prestigious scientific academic partners and industrials

The Strong Demand From Physicians Resulting From The High Unmet Medical Needs Opens A Complementary Market Access Business Model

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

(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

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

PHAXIAM Has Strong Clinical Development and Market Access Capabilities in the PTMP[1] Model

PTMP

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

November 2024

(1) Pre-defined (standardized) finished product consisting of one or more bacteriophage strains
(2) AAC = Authorization for Compassionate Access → **Compassionate Use (CU)**

New Near Term Commercial Opportunities Arise From the Emergence of the Individualized Phages Therapy (IPT[1]) Market Access Model

IPT

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

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

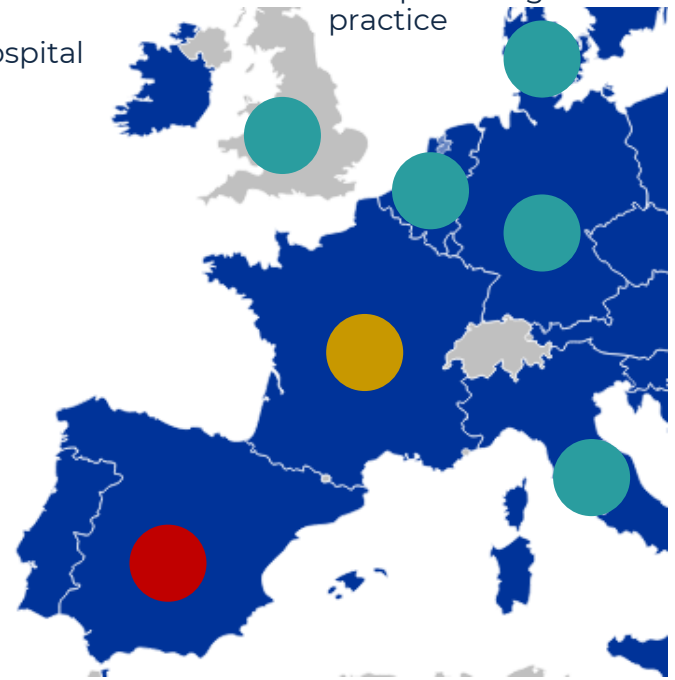
IPT

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

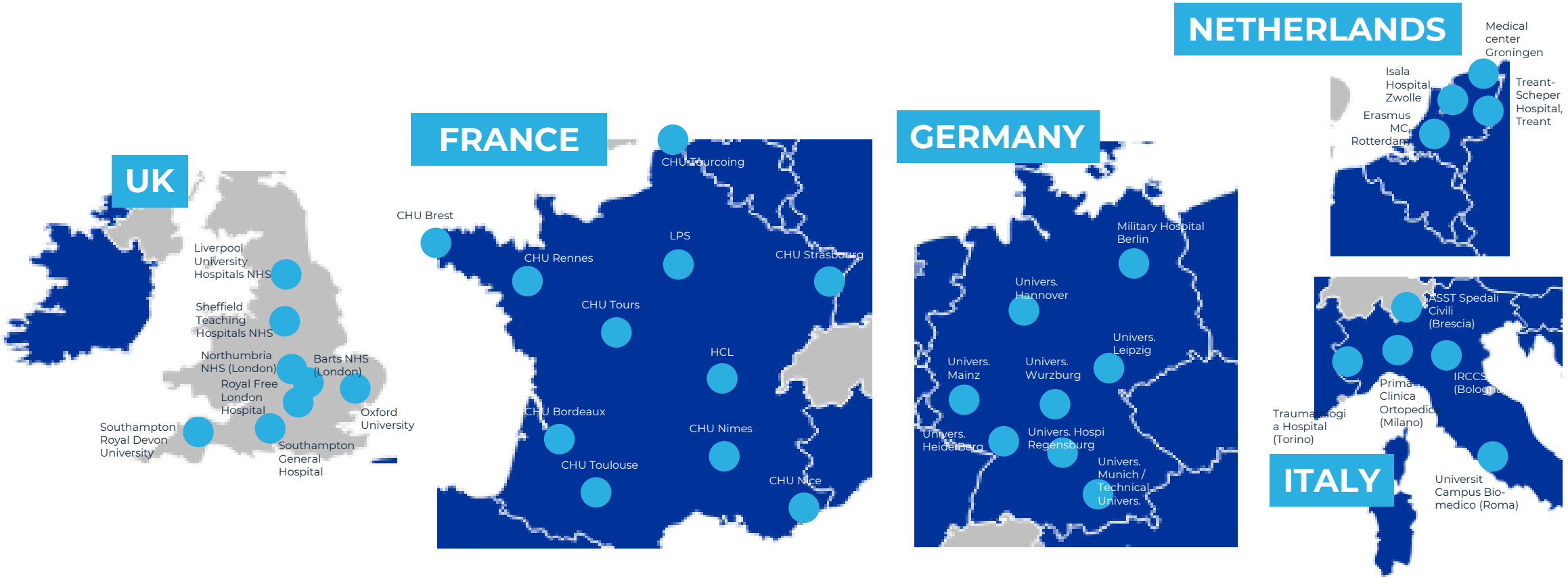
Increasing Interest From Physicians For Phages All Over Europe
Magistral Preparation / Compounding Are Common Practices In Northern Europe

(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

PHAXIAM Already Interacts With Large EU Reference Hospitals In Its PTMP Clinical Development Efforts

PTMP

IPT



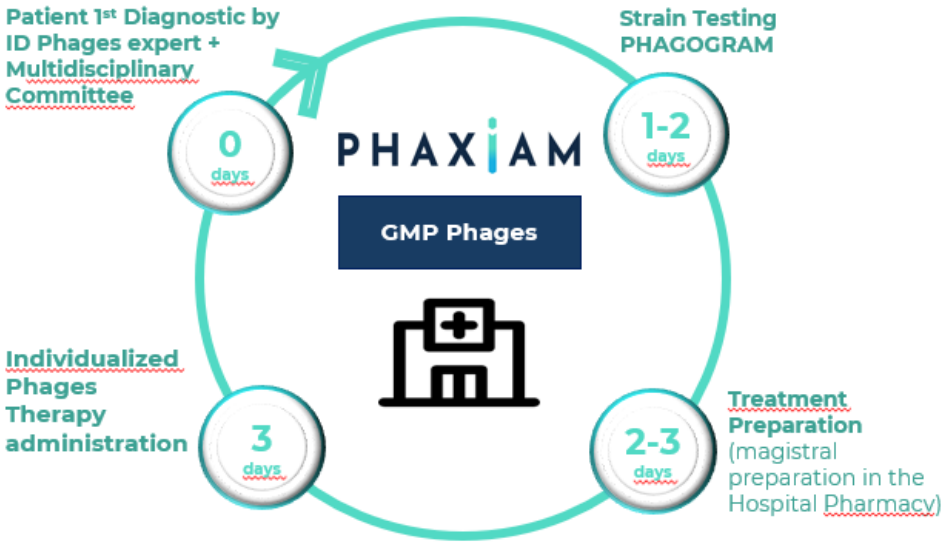
EU Clinical Sites Participating In PHAXIAM Studies (GLORIA) Can Be Leveraged To Accelerate The IPT Commercial Uptake

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 transferred**



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 Complementary And Synergistic Market Channels With Largely Overlapping Requirements

Complementarities & Synergies

Individualized Phages Therapy (IPT)

- Leveraging PHAXIAM's GMP Phages Registry (>30 GMP phages) for the 7 most important pathogens
- Access to Physicians / Pharmacists at hospital level in largest hospitals
- Formal national regulatory validation for the use of phages
- Individualized treatment with a Diagnostic test (Phagogram – CE marked)

Phages Registry

GMP Manufacturing

Relationships with KOLs & Reference hospitals

Relationships with Regulatory Authorities

Diagnostic Test

Phage Therapy Medicinal Product (PTMP)

- 10-15 GMP phages of 3 main pathogens (SA, PA, EC)
- Already received 1st Regulatory validation (AAC) from ANSM and IND from FDA (Phase II POC)
- Large number of clinical sites (~45 sites) in GLORIA study
- POC demonstration with RCTs
- Use of a Diagnostic test (Phagogram – CE marked), when required

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

PHAXIAM Is An Emerging Paneuropean Specialty Pharma in Critical Care Targeting Significant Revenues Achievements

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**

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

(1) Targeted Addressable Market

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Building a Global Phages Therapy Leader

"Critical Needs for "Individualized Phages Treatments" in Europe"

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Round Table – Experts Panel
Critical Need for "Individualized Phages Treatments" in Europe

- Dr. **Robert Sebbag** (MD, Infectiologist, La Pitié-Salpêtrière – Paris)

- Dr. **Antonia Scobie** (MD, Infectiologist, Royal Free London NHS Foundation Trust – London)

- Prof. Dr. med. **Volker Alt** (MD, Director and Chairman of Department of Trauma Surgery University Medical Centre – Regensburg)

- Dr. **Truong-Thanh PHAM** (MD, Infectiologist, Hôpitaux Universitaires de Genève – Genève)

Round Table – Questions
Critical Need for "Individualized Phages Treatments" in Europe

ROUND TABLE – "Critical Needs for Individualized Phages Therapies in Europe"
(Experts panel; 30')

Question 1 How Do You Evaluate In Your Country The Needs For Phages Therapies To Treat Various Kind Of Severe Resistant Infections?

Question 2 In Parallel To Robust Clinical Development Efforts (PTMP), Where Do you See Value In Delivering **Individualized Phages Therapies** (IPT) To The Patients?

Question 3 According To You, What Are The Challenges And PHAXIAM's Special Contribution In Delivering **Individualized Phages Therapies** (IPT) To Patients?

PHAXIAM, An Emerging Specialty Pharma In Critical Care

- **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.**

Based On These Developments, PHAXIAM Could Reach Operating Profitability And Positive Free Cash Flow In 2027

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

MA, mandatory for products containing **Allergens responsible for common allergies**

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

Drug Product (GMP)

Pre-clinical

Clinical

Phase I

Phase II

Phase III

Market Authorization **Can be sold**

Allergens Therapy Medicinal Products

- Allergen-bulk mixtures prepared for a single individual patient
- Option for Patients whose allergies cannot be treated with alternative authorised allergen products **OR** low prevalence allergies

Derogation Path without MA[1]

Named-patient Programs (NPP)

API
GMP Raw materials

Magistral Preparation

With GMP Allergen Bulk (DS)
Can be sold

Under the Physician's responsibility / Prepared at the Hospital Pharmacy

Individualized Allergens Treatment

(1) Market Authorization