PHAXIAM Provides Business and Financial Update For the First Half of 2024

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- **Continuous commitment to create a global leader in phage therapies to treat severe and resistant bacterial infections**
- **Ambitious development strategy on track with clear objectives set for the Prosthetic Joint Infections (PJI) strategic program**
  - Clinical readout expected before end of year 2024, including Updated Compassionate real life clinical data and PhagoDAIR pilot study
  - Imminent Filing of Investigational New Drug Application (IND) in US and Clinical Trial Application (CTA) in Europe for GLORIA, the first global GLORIA Phase II study for the treatment of Staphylococcus aureus infections of PJI, with the aim of approval by the US and European regulatory agencies expected in Q4 2024
  - Launch of the 1st global GLORIA Phase II study in Prosthetic Joint Infections (PJI) expected in Q1 2025
- **Cash and cash equivalents of €1.5 million as of June 30, 2024, not including the €6.8 million net proceeds from the capital increase, which was settled in early July 2024**

Lyon (France), September 25, 2024 at 5:45 pm CEST – PHAXIAM Therapeutics (Euronext: PHXM), a biopharmaceutical company developing innovative treatments for severe and resistant bacterial infections, today provides a business and financial update for the first half of 2024.

"Since the beginning of 2024, all PHAXIAM teams have been very committed and focused on the submission of the GLORIA Phase II study protocol to the American and European authorities and on the preparation of the launch of this study, expected in the first quarter of 2025. With the IND (U.S.) and CTA (EU) about to be very shortly filed, the most important catalyst of our development strategy is in reach. In addition, clinical data from PhagoDAIR, our pilot study, are expected in late 2024, as planned." stated **Thibaut du Fayet, Chief Executive Officer of PHAXIAM.**

BUSINESS HIGHLIGHTS

- **Phage therapy strategy focused on high-value indications**

PHAXIAM has refocused its clinical development on programs targeting patients with severe resistant infections of high medical needs, associated with high mortality and budget impact.
Significant progress has been achieved over the year 2024 to accelerate PHAXIAM's strategy deployment on key therapeutic programs, particularly with its lead program targeting Prosthetic Joint Infections caused by *Staphylococcus aureus (S. aureus)*.

- **Clinical and regulatory strategy in *S. aureus* program on track**

With its lead *S. aureus* program, PHAXIAM pursues the ambition to propose a therapeutic solution to patients who failed traditional antimicrobial treatments in complex mono-bacterial *S. aureus* infections in several high-value indications.

- **Prosthetic Joint Infections (PJI): toward the first global Phase II study, enabling a potential Early Access Pathway**

Leveraging on promising activity signals from real-life compassionate treatments, with more than 120 patients already treated (data to September 2024), PHAXIAM is preparing the initiation of the 1st global (EU/US) Phase II POC study (GLORIA) for PJI patients (Hip or Knee prosthesis) having an open-surgery debridement (DAIR) in combination with antibiotics.

As planned, PHAXIAM aims to:

1. deliver PhagoDAIR pilot study preliminary data at the end of 2024, and the study's complementary data in 2025,
2. accelerate the transitioning of PJI clinical development effort into the ambitious global Phase II proof-of-concept study (GLORIA) to be launched in Q1 2025.

GLORIA is PHAXIAM's most important asset, having the highest priority. This multicentric, randomized, comparative Phase II proof-of-concept study, is expected to enroll 100 patients in Europe and the US.

PHAXIAM is about to file the Investigational New Drug Application (IND) and the Clinical Trial Application (CTA) to US and European regulatory agencies respectively. The formal approval of the study is expected in Q4 2024, in view of starting patient enrollment in Q1 2025.

Upon a successful completion of GLORIA Phase II study anticipated in Q3 2026, PHAXIAM may be eligible to an Early Access Pathway, paving the way for a pre-commercialization in Europe as soon as H2 2027.

- **Endocarditis Infections (EI): patients' enrolment ongoing in five French sites**

This Phase I PK study enrolls patients with resistant *S. aureus* infections in the cardiac chambers and valves.

First clinical results are now expected around mid-2025. If positive, these results could allow PHAXIAM to:

1. accelerate a clinical development in this indication; and
2. use the intravenous (IV) administration for other indications requiring this administration route.

- **Clinical study in complex mono-bacterial *Escherichia coli (E. coli*) infections, validated and ready for enrolment**

The objective of this *E. coli* program, including a Phase I PK study validated by the French Health Authority (ANSM), is to propose a therapeutic solution to patients having failed traditional antimicrobial treatment in complex mono-bacterial *E. coli* infections in the urinary tract.

- **Confirmed valuable real-life clinical benefit data from compassionate treatments with more patients coming from European countries**

To date, PHAXIAM has treated more than 120 patients under compassionate treatment status, most of them suffering from hip or knee PJI. The vast majority is located in France but more and more compassionate patients, stemming from other European countries, are treated in their country with PHAXIAM phages: Sweden, Switzerland, Latvia, Romania and United Kingdom.

Data from the first 77 patients evaluated so far show promising results with infection control at 3 months (clinical endpoint) reaching approximately 80%, considered as a significant improvement over standard of care (SoC) in this hard-to-treat patient population with severe resistant infections, often undergoing 2nd or 3rd line SoC antibiotic treatment.

Early 2025, PHAXIAM is planning to file for another AAC (*Autorisation d'Accès Compassionnel* – early access program), in order to bring a new compassionate treatment to PJI patients associated with *Pseudomonas aeruginosa (P. aeruginosa)* resistance, complementing the first obtained AAC, associated with *S. aureus* resistance.

- **Complementary Investigator-sponsored trials (IST)**

In addition to PHAXIAM's sponsored clinical studies, two other investigator-sponsored trials, in which PHAXIAM is highly involved, are the opportunity to deliver additional clinical POC data in other high-value indications:

- Phase II study (60 patients) in Diabetic Foot Ulcer (DFU): this clinical study, sponsored by Nîmes Hospital, targets DFU infections due to mono-bacterial *S. aureus* infection; this study is ready for First-Patient-In, expected before the end of this year.
- Phase II study (180 patients) in complex Respiratory Tract Infections (cUTI): this clinical study, sponsored by La Pitié Salpêtrière Hospital in Paris, targets nosocomial pulmonary infections due to *P. aeruginosa*, including patients with ventilator-associated pneumopathies (VAP), a growing concern in hospital environments. The filing of this study is planned in France (ANSM) in Q1 2025.

H1 2024 FINANCIAL RESULTS

Key financial figures for the first half of 2024 compared with the same period of the previous year are summarized below.

As a reminder, PHAXIAM's consolidated financial statements in IFRS standards for H1 2023 include ex-Pherecydes financial results as of the date of the merger, i.e. June 23, 2023. Consequently, PHAXIAM's P&L information for the first 6 months of 2023 are mostly related to ex-Erytech activities only, while PHAXIAM's consolidated balance sheet as of June 30, 2023, includes the financial positions of both merged companies.

The full Financial Statements of PHAXIAM Therapeutics as of June 30, 2024 has been filed with the AMF on Wednesday, September 25, 2024, and is available on the company's website.

In thousands of euros	**H1 2024 (6 months)**	**H1 2023 (6 months)**
Revenues	—	—
Other income	1,093	278
Operating income	**1,093**	**278**
Research and development	(6,406)	(3,431)
General and administrative	(5,345)	(9,245)
Operating expenses	**(11,751)**	**(12,676)**
Operating income (loss)	**(10,658)**	**(12,398)**
Financial income	175	331
Financial expenses	(132)	(342)
Financial income (loss)	**43**	**(11)**
Income tax	(20)	203
Net loss	**(10,635)**	**(12,201)**

Operating expenses of €11.7 million in the first half of 2024 were 7% lower (i.e. a €0.9 million reduction) than in the same period of the previous year. This decrease was driven by the 42% reduction of G&A expenses, including €3.4 million of non-recurring merger cost and €0.5 million of additional savings following Nasdaq delisting.
This cost-cutting program was accelerated in the third quarter of 2024 to be in place as part of the 2025 budget.

PHAXIAM's operational R&D expenses in the first half of 2024 increased by €1.4 million (+41%) mostly on S. aureus development program, not included in the previous year's comparison. In addition, an impairment charge of €1.5 million on the endocarditis IP (EnDoCom) has been recorded.

Net loss for the first half of 2024 was €10.6 million, compared with a net loss of €12.2 million for the same period of 2023.

As of June 30, 2024, PHAXIAM had cash and cash equivalents totaling €1.5 million, compared with €10.5 million as of December 31, 2023. The €9 million decrease in cash position during the first half of 2024 was the result of a €8.2 million net cash utilization in operating activities including ~ €1 million in severance costs, €0.5 million in investing activities and €0.5 million used in financing activities, mostly related to lease reimbursement.

On July 1, 2024, with the settlement & delivery of the €7.8 million capital increase, PHAXIAM's cash position increased by a net €6.8 million, after payment of capital increase costs.

The Company believes that its current cash position can fund its existing programs and expected operating expenses into March 2025. The Company is studying all options to extend its financial visibility: cost reduction program, obtaining non-dilutive financing at the national and European level, search for strategic and institutional investors, etc.

MANAGEMENT TEAM EVOLUTION

Eric Soyer, former CFO / COO, is leaving PHAXIAM to pursue other interests. Frédéric Mathat succeeds him and will lead the Company's Finance department as CFO.
After a first robust experience in accounting and consolidation of listed companies (8 years at Nexity, the real estate branch of Vivendi, then 7 years at Sequana), Frédéric had been financial director of the Canson group for 11 years. He joined the pharmaceutical industry in 2017 to lead Erytech's finance department alongside Eric Soyer, until the merger with Pherecydes, in which he was instrumental and committed all along the process that led to the creation of PHAXIAM.

Thibaut du Fayet, Chief Executive Officer of PHAXIAM, commented: *"I would like to warmly thank Eric Soyer for his dedication during these 8 years spent at Erytech where he performed several fundraisings on Nasdaq and Euronext public markets, then at PHAXIAM where he was very instrumental in the success of the merger, as his contribution has been essential in designing PHAXIAM's strategy; I wish him all the best for the near future. I am also delighted to welcome Frédéric as Chief Finance Officer. His extensive expertise and proven track record in finance add great value to our team."*

KEY NEWSFLOW AND MILESTONES EXPECTED OVER THE NEXT 12 MONTHS

- Phase II IST in Diabetic Foot Ulcer (DFU) First-Patient-In expected in Q4 2024
- PhagoDAIR pilot study clinical readout expected before end of year 2024
- GLORIA global Phase II IND and CTA validation expected in Q4 2024
- GLORIA global Phase II First-Patient-In expected in Q1 2025
- Endocarditis Phase I PK study first readout expected around mid-2025

FIRST HALF 2024 WEBINAR DETAILS

PHAXIAM management will hold a webinar today, **Wednesday, September 25, 2024, at 6:00 pm CEST** on the business highlights and financial results for the first half of 2024. Thibaut du Fayet, (CEO) and Frédéric Mathat (CFO), will deliver a brief presentation in French, followed by a Q&A session.

The webinar, held in French, is accessible via **this registering link.**

The replay of the webinar will be available on the Company's website in the following days.

About PHAXIAM Therapeutics

PHAXIAM is a biopharmaceutical company developing innovative treatments for resistant bacterial infections, which are responsible for many serious infections. The company is building on an innovative approach based on the use of phages, natural bacterial-killing viruses. PHAXIAM is developing a portfolio of phages targeting 3 of the most resistant and dangerous bacteria, which together account for more than two-thirds of resistant hospital-acquired infections: Staphylococcus aureus, Escherichia coli and Pseudomonas aeruginosa.

PHAXIAM is listed on the Euronext regulated market in Paris (ISIN code: FR0011471135, ticker: PHXM). PHAXIAM is part of the CAC Healthcare, CAC Pharma & Bio, CAC Mid & Small, CAC All Tradable, EnterNext PEA-PME 150 and Next Biotech indexes.

For more information, please visit www.phaxiam.com

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Forward-looking information

This press release contains forward-looking statements, forecasts and estimates with respect to the clinical programs, development plans, business and regulatory strategy and anticipated future performance of PHAXIAM and of the market in which it operates. Certain of these statements, forecasts

and estimates can be recognized by the use of words such as, without limitation, “believes”, “anticipates”, “expects”, “intends”, “plans”, “seeks”, “estimates”, “may”, “will” and “continue” and similar expressions. All statements contained in this press release other than statements of historical facts are forward-looking statements. Such statements, forecasts and estimates are based on various assumptions and assessments of known and unknown risks, uncertainties and other factors, which were deemed reasonable when made but may or may not prove to be correct. Actual events are difficult to predict and may depend upon factors that are beyond PHAXIAM's control. Therefore, actual results may turn out to be materially different from the anticipated future results, performance or achievements expressed or implied by such statements, forecasts and estimates. Investor should carefully read the risk factors section of the Company which can be found in the Company’s regulatory filings with the French Autorité des Marchés Financiers (AMF), including in the Company’s 2023 Universal Registration Document (Document d’Enregistrement Universel) filed with the AMF on April 5, 2024 and future filings and reports by the Company. Given these uncertainties, no representations are made as to the accuracy or fairness of such forward-looking statements, forecasts and estimates. Furthermore, forward-looking statements, forecasts and estimates only speak as of the date of this press release. PHAXIAM disclaims any obligation to update any such forward-looking statement, forecast or estimates to reflect any change in PHAXIAM’s expectations with regard thereto, or any change in events, conditions or circumstances on which any such statement, forecast or estimate is based, except to the extent required by law.

Attachment

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