PHAXIAM

PRESS RELEASE

PHAXIAM Provides Business and Financial Update For the First Half of 2023

Conference call and webcast (English) on Monday, September 25, 2023
at 8:30am ET / 2:30pm CEST

- **Formation of PHAXIAM Therapeutics effective as of June 23, 2023, to create a global leader in phage therapies for high-value indications**
- **Ambitious strategy to develop value-creating clinical and regulatory plan in severe and resistant bacterial infections**
  - Plan to launch new and first phase 2b/3 global pivotal study in Prosthetic Joint Infections (PJI) in 2H 2024
  - Interactions with FDA (Pre-IND) and EMA (Scientific advice) planned in Q4 2023, to finalize the design of the Phase 2b/3 study in PJI
  - Plan to launch Phase 1 study in Endocarditis Infections in Q4 2023
- **Cash and cash equivalents of €25.2 million ($27.5 million) as of June 30, 2023**

Lyon (France) et Cambridge (MA, US), September 21, 2023 at 10:05pm CEST – PHAXIAM Therapeutics (Nasdaq & Euronext: PHXM), today provides a business and financial update for the first half of 2023.

"With the merger effective since the end of June, all PHAXIAM teams have now been driving PHAXIAM reinforced Phage Therapy strategy, by developing clinical programs in high-value indications and accelerating their path to registration," said **Thibaut du Fayet, Chief Executive Officer of PHAXIAM.** *"Our team complementarities are now in action, with already significant progress made on the clinical and regulatory front to further advance our lead Staphylococcus aureus program, with notably the ongoing preparation of the first global Phase 2b/3 study in PJI and related filings of meeting requests with the FDA and EMA. At times when antimicrobial resistance is an ever-growing concern in Europe and in the US, considered as a 'Silent Pandemics', PHAXIAM is now very well positioned to become a global leader in the fight against severe and resistant infections of very high medical needs."*

BUSINESS HIGHLIGHTS

a) Phage Therapy strategy focused on key, high-value indications

PHAXIAM has been refocusing its clinical development programs in indications of high medical needs, for patients with severe resistant infections, often associated with high mortality and budget impact. Significant progress has been achieved since the merger to build on team synergies and accelerate PHAXIAM's strategy deployment on key therapeutic programs, particularly with its lead program targeting resistant Staphylococcus aureus infections.

b) Clinical development: significant progress on Clinical and Regulatory strategy toward a registration study in PJI

- **Staphylococcus aureus (S. aureus) program**

  - 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 different high-value indications.

- Leveraging on promising activity signals from real-life treatments of compassionate patients, PHAXIAM is preparing the initiation of the first global (EU/US), pivotal randomized Phase 2b/3 study for PJI patients having an open-surgery debridement (DAIR) in combination with antibiotics.

- While developing the clinical protocol of the study, PHAXIAM has requested this summer a pre-IND meeting with the U.S. FDA and a Scientific Advice meeting with the European Medicines Agency (EMA). Meetings are expected to happen in Q4 2023. This global pivotal study is paving the way for a potential Early access pathway in Europe, if associated with positive phase 2b data.

- PHAXIAM is also preparing a phase 1 trial (PK data) in Endocarditis Infections (EI), to demonstrate intravenous administration of phages for EI and other indications.

Program	Status and Progress
Prosthetic Joint Infections (Hip / Knee) New Phase 2b/3 And PhagoDAIR	• *PJI patients having a DAIR in combination with SOC antibiotics* • *Phages administered locally* • *Safety evidence already demonstrated in current PhagoDAIR study* • *Plan to launch ambitious efficacy study in a large global registration Phase 2b / 3 trial* **Recent updates** **Phase 2b/3** • Pre-IND meeting (FDA) and a Scientific Advice (EMA) expected to happen in Q4 2023 • Potential Phase 2b/3 study launch expected in H2 2024 **PhagoDAIR pilot study** • Additional supportive clinical data expected in 2024
Endocarditis Infections (EI) Phase 1 PK	• *EI patients having resistant infections in the cardiac chambers and valves* • *Phages administered intravenously* • *Expected assessment of the PK and PD of the IV route in the EI indication , potentially leading to the registration in EI and other indications where the IV route is the recommended mode of administration* **Recent updates** • First Patient-In expected in Q4 2023

- ***Escherichia coli* (E. coli) program**

The objective of this program is to propose a therapeutic solution to patients having failed traditional antimicrobial treatment in complex mono-bacterial E. coli infections in the urinary tract.

Complex Urinary Tract Infections (cUTI) Phase 1 PK	• *cUTI patients with resistant E. Coli infections in the bladder* • *Phages administered through a catheter into the bladder* • *Expected demonstration of intra-bladder route of administration (PK data) before moving to registration study* **Recent updates** • CTA submission in France planned before end of year 2023

- ***Valuable real-life efficacy data from compassionate treatments***

To date, PHAXIAM has treated more than 90 patients under compassionate treatment status, most of them suffering from hip or knee PJI. Data from the first 50 PJI patients evaluated show promising clinical data for infection control at 3 months, considered as a significant improvement over standard of care in this hard-to-treat patient population with severe resistant infections.

In June 2022, PHAXIAM has received a first regulatory validation from the French ANSM with the granting of an AAC (*Authorisation d'Accès Compassionnel – early access program*) for PJI patients, associated with S. aureus resistance. The company is awaiting a second AAC regulatory validation for PJI patients, associated with P. aeruginosa resistance from the ANSM.

- ***Investigator-sponsored trials***

In addition to PHAXIAM's clinical activities, two French clinical centers are considering Investigator-Sponsored Trials (IST) with PHAXIAM's products. These studies are the opportunity for PHAXIAM to potentially deliver additional clinical POC data in other high-value indications:

- Phase 1/2 IST in complex Respiratory Tract Infections (cUTI): this clinical study by La Pitié Salpétrière Hospital in Paris, is targeting nosocomial pulmonary infections due to *Pseudomonas aeruginosa*, including patients with ventilator-associated pneumopathies (VAP), a growing concern in hospital environments.
- Phase 1/2 IST in Diabetic Foot Ulcer (DFU): this clinical study by Nîmes Hospitals, is targeting DFU infections due to mono-bacterial Staphylococcus aureus infection.

c) Preclinical research programs initiated to reinforce PHAXIAM's phage therapy platform

PHAXIAM has launched several strategic research programs to reinforce its current clinical programs and prepare future developments, including the extension of the current phage bank for E. coli and P. aeruginosa to increase patient resistant infections coverage, and the demonstration a Pre-clinical POC for Endolysins.
On September 19, 2023, the company announced the extension of its portfolio to Klebsiella pneumoniae, a new resistant aggressive bacterial target.

A strategic research program, PhageBac, targeting Bacteremia, has been initiated. Currently at preclinical stage, this program is aiming at controlling blood infection and the risk of secondary infection with mono-bacterial infection due to S. aureus, P. aeruginosa, or E. coli. Pre-clinical data are expected for mid-2024.

1H 2023 FINANCIAL RESULTS

Key financial figures for the first half of 2023 compared with the same period of the previous year are summarized below. In the context of the Erytech-Pherecydes merger, PHAXIAM's consolidated financial statements in IFRS standards 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 30,2023 will be filed with the AMF and the SEC on Monday, September 25, 2023, and will be available on the company's website at that date.

In thousands of euros	**1H 2023 (6 months)**	**1H 2022 (6 months)**
Revenues	—	—

Other income	278	954
Net gain on asset sale	—	24,351
Operating income	**278**	**25,304**
Research and development	(3,431)	(17,300)
General and administrative	(9,245)	(7,911)
Operating expenses	**(12,676)**	**(25,211)**
Operating income (loss)	**(12,398)**	**93**
Financial income	331	3,370
Financial expenses	(342)	(750)
Financial income (loss)	**(11)**	**2,620**
Income tax	203	(3,737)
Net loss	**(12,201)**	**(1,024)**

Operating expenses of €12.7 million in the first half of 2023 were 50% lower (i.e. a €12.5 million reduction) than in the previous year, the decrease being driven by the 80% reduction of R&D expenses, with the closing of Princeton operations and the termination of ex-Erytech clinical development activities. PHAXIAM's G&A expenses in the first half of 2023 increased by €1.3 million (+17%) versus the previous year, an increase related to the merger transaction and other merger-related costs. Net loss for the first half of 2023 was €12.2 million, compared with a net loss of €1 million for the same period of 2022, which benefited from the €24.4 million net gain on the sale of the Princeton facility in April 2022.

As of June 30, 2023, PHAXIAM had cash and cash equivalents totaling €25.2 million (approximately $27.5 million), compared with €38.8 million as of December 31, 2022. The €13.6 million decrease in cash position during the first half of 2023 was the result of a €12.1 million net cash utilization in operating activities and investing activities and €1.6 million used in financing activities, mostly related with the start in 2023 of the reimbursement of the 'PGE', Covid-loan, while the variation of the U.S. dollar against the euro led to a €0.3 million negative currency exchange impact.

The Company believes that its current cash position can fund its current programs and planned operating expenses into the second quarter of 2024.

COMPLETION OF THE REVERSE SHARE SPLIT

On September 18, 2023, PHAXIAM announced the completion of its reverse share split on ordinary shares and ADRs. The reverse share split involved the exchange of ten (10) existing shares with a par value of ten-euro cents (€0.10) for one (1) new share with a par value of one euro (€1). This reverse share split has no impact on the Company's share capital and results in the division of the number of shares outstanding by ten, and a multiplication by ten of the par value of each share. With this reverse stock split now effective, the Company intends to regain compliance with The Nasdaq Global Select Market minimum $1 bid price requirement.

KEY NEWSFLOW AND MILESTONES EXPECTED OVER THE NEXT 12 MONTHS

- Regulatory feedbacks on the Ph 2b/3, pivotal trial in PJI (S. aureus) from the FDA (Q4 2023) and the EMA (Q1 2024) and expected trial initiation in 2H 2024
- Initiation of the Endocarditis study (S. aureus) in Q4 2023
- PhagoDAIR clinical data: 2H 2024

FIRST HALF 2023 CONFERENCE CALL DETAILS

PHAXIAM management will hold a conference call and webcast on **Monday, September 25, 2023, at 8:30am ET / 2:30pm CEST** on the business highlights and financial results for the first half 2023. Thibaut

du Fayet, CEO, and Eric Soyer, COO/CFO, will deliver a brief presentation in English, followed by a Q&A session.

The audio call is accessible via the below registering link:
https://register.vevent.com/register/BI040b7d9e837d4a61a258d2846b3ad57a.

Once registered, participants will receive a unique access code and the call number details to join the teleconference.

The webcast can be followed live online via the link: **https://edge.media-server.com/mmc/p/b3iyj85y**

In addition, the replay of the webcast will be available for a period of one year on this same link.

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 Nasdaq Capital Market in the United States (ticker: PHXM) and 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

Contacts

PHAXIAM
Eric Soyer
COO & CFO
+33 4 78 74 44 38
investors@phaxiam.com

NewCap
Mathilde Bohin / Dušan Orešanský
Investor Relations
Arthur Rouillé
Media Relations
+33 1 44 71 94 94
phaxiam@newcap.eu

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. Important factors that could cause actual results and outcomes to differ materially from those indicated in the forward-looking statements include, among others, the following: (1) the inability to maintain the listing of PHAXIAM’s shares on the Nasdaq Capital Market and the Euronext regulated market; (2) changes in applicable laws or regulations; (3) the possibility that PHAXIAM may be adversely affected by other economic, business and/or competitive factors; and (4) other risks and uncertainties indicated from time to time in PHAXIAM’s regulatory filings. Further description of these risks, uncertainties and other risks can be found in the Company’s regulatory filings with the French Autorité des Marchés Financiers (AMF), the Company’s Securities and Exchange Commission (SEC) filings and reports, including in the Company’s 2022 Universal Registration Document (Document d’Enregistrement Universel) filed with the AMF on March 28, 2023 and in the Company’s Annual Report on Form 20-F filed with the SEC on March 28, 2023 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. Readers are cautioned not to place undue reliance on any of these forward-looking statements. 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.