

PHAXIAM Provides Business and Financial Update for the Third Quarter of 2023

Conference call and webcast (English) on Wednesday, November 15, 2023
at 8:30am ET / 2:30pm CET

- **Ambitious clinical development strategy progressing to create a global phage therapy leader in high-value indications**
- **Early access program continues to gain momentum with the treatment of more than 90 patients suffering from severe and resistant infection prosthetic joint infections of the hip or knee (PJI)**
- **Cash and cash equivalents of €15.6 million (\$16.5 million) as of September 30, 2023**

Lyon (France) et Cambridge (MA, US), November 14, 2023, at 10:05pm CET – PHAXIAM Therapeutics (Nasdaq & Euronext: PHXM), a biopharmaceutical company developing innovative treatments for severe and resistant bacterial infections, today provides a business and financial update for the third quarter of 2023.

“The third quarter of 2023 was a prolific period during which we managed to move forward with our development programs and benefited from the complementarities of our teams in the context of the merger completion” stated Thibaut du Fayet, Chief Executive Officer of PHAXIAM Therapeutics. “Regarding our clinical plan, we obtained valuable feedback from the FDA confirming the value of our main asset, anti-S. aureus Phages, for a development in the United States. We plan to design a global consolidated development plan once we get the EMA scientific advice feedback in the coming weeks. In parallel, the enrolment of the first patient in our Phase 1 endocarditis infections study, expected around the end of the year, will be another major step forward for PHAXIAM in its strategic positioning to target indications of very high clinical value.”

BUSINESS HIGHLIGHTS

a) Confirmed strategic focus on Phage Therapy in 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. This quarter’s clinical progress of PHAXIAM’s key therapeutic programs, particularly with its lead program targeting resistant *S. aureus* infections, confirms the Company’s advanced positioning in phage therapy.

b) Significant progress in the Clinical and Regulatory strategy

- **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 several high-value indications, starting with Prosthetic Joint Infections and Endocarditis Infections.

- **Prosthetic Joint Infections (PJI)**
 - Leveraging on promising activity signals from real-life compassionate treatments, PHAXIAM is preparing the initiation of a global (EU/US) study for PJI patients having an open-surgery debridement (DAIR) in combination with antibiotics.
 - PHAXIAM received feedback from FDA on the next steps for its clinical development plan in PJI, with the following key points:
 - Confirmation of the value of a clinical development in this indication,
 - Confirmation that PHAXIAM's non-clinical data and CMC capabilities support a formal clinical development plan in the US,
 - FDA provided PHAXIAM with clear guidelines for a Phase 2 study in the US.
 - A Scientific Advice meeting with the European Medicines Agency (EMA) is expected to take place in January 2024 and its outcomes, combined with the recommendations from the FDA, will be the basis to design PHAXIAM's future global (EU/US) clinical plan in PJI.
- **Endocarditis Infections (EI)**
 - PHAXIAM is preparing the launch of a phase 1 trial (PK data) in Endocarditis Infections caused by *S. aureus*, to evaluate intravenous administration of phages for EI. The results, if positive, could allow PHAXIAM to use this administration route for other indications.
 - In October, PHAXIAM obtained approvals from the French ANSM and South-East II-Lyon Ethics Committee to launch the study that should enroll 12 patients requiring replacement of an infected heart valve.
 - The enrollment is targeted to start by the end of 2023 and the first study results are expected in mid-2024.

● **Robust real-life activity data from compassionate treatments**

In June 2022, the ANSM granted PHAXIAM an AAC (*Autorisation d'Accès Compassionnel – early access program*) and to date, more than 90 patients have been treated under the compassionate/AAC status. Data from the first 77 PJI patients evaluated so far 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.

The Company has applied for a second AAC regulatory validation for PJI patients, associated with *P. aeruginosa* resistance.

c) **Confirmed efficiency of Phagogram, PHAXIAM's proprietary platform to assess phage activity**

Phagogram is an *in vitro* diagnostic (IVD) test designed to determine the *in-vitro* activity of PHAXIAM's phages to patients' bacterial strains. It is the first CE-marked IVD test dedicated to phage activity evaluation.

In October 2023, the Company announced that the data obtained from Phagogram showed 98% response rate over 105 clinical *S. aureus* strains, showing the highest spectrum of activity of the anti-*S. aureus* phages among other competing solutions.

These data clearly demonstrate the efficiency of PHAXIAM's phagogram for the current and upcoming clinical developments. It also proves how it is a unique asset for the development of other phages in PHAXIAM's portfolio.

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

PHAXIAM launched several strategic research programs to reinforce its current clinical programs and prepare future developments, including with the extension of the current phage bank for *E. coli* and *P. aeruginosa* to increase resistant infections coverage and the demonstration of 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, very complementary to the first 3 pathogens (*S. aureus*, *P. aeruginosa*, *E. coli*)
- 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*.
- In October 2023, PHAXIAM concluded a strategic research partnership with Vetophage, a biotechnology company specialized in veterinary phage therapy, to combine expertise in the research of new phages and phage endolysins. This agreement provides PHAXIAM with exclusive licensing options on specified phages and endolysins from the Vetophage platform, to further strengthen its product portfolio in human health.

Q3 2023 FINANCIAL RESULTS (unaudited)

Key financial figures for the first nine months 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 from the date of the merger, i.e. June 23, 2023. Consequently, PHAXIAM's P&L information for the first 9 months of 2023 include 9 months of ex-Erytech activities and ex-Pherecydes activities since June 23, 2023.

<i>In thousands of euros</i>	Q3 2023 ytd 9 months (unaudited)	Q3 2022 ytd 9 months (unaudited)
Revenues	—	—
Net income from asset sale	9	24,351
Other income	475	1,423
Operating income	484	25,774
Research and development	(6,756)	(20,377)
General and administrative	(11,875)	(10,870)
Operating expenses	(18,631)	(31,248)
Operating income (loss)	(18,147)	(5,474)
Financial income	465	4,031
Financial expenses	(417)	(881)
Financial income (loss)	48	3,150
Income tax	208	(3,838)
Net loss	(17,891)	(6,163)

Operating expenses of €18.6 million in the first nine months of 2023 were 40% lower (i.e. a €12.6 million reduction) than in the previous year, the decrease being driven by the 67% reduction of R&D expenses, mostly driven by the closing of Princeton operations and the termination of ex-Erytech clinical development activities. PHAXIAM's G&A expenses in the first nine months of 2023 increased by €1.0 million (+9%) versus the previous year, an increase related to the merger transaction and other merger-related costs. Net loss for the first nine months of 2023 was €17.9 million, compared with a net loss of €6.2 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 September 30, 2023, PHAXIAM had cash and cash equivalents totaling €15.6 million (approximately \$16.5 million), compared with €38.8 million as of December 31, 2022. The €23.2 million decrease in cash position during the first nine months of 2023 was the result of a €20.5 million net cash utilization in operating activities and investing activities and €2.6 million used in financing activities, mostly related to the reimbursement of the 'PGE' Covid-loan, while the variation of the U.S. dollar against the euro led to a €0.1 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.

KEY NEWSFLOW AND MILESTONES EXPECTED OVER THE NEXT 12 MONTHS

- Regulatory feedback from the EMA on the next clinical development in PJI (*S. aureus*) (Q1 2024)
- First Patient-In for Endocarditis study (*S. aureus*) (around year-end 2023)
- PhagoDAIR clinical data (H2 2024)

Q3 2023 CONFERENCE CALL DETAILS

PHAXIAM management will hold a conference call and webcast on **Wednesday, November 15, 2023, at 8:30am ET / 2:30pm CET** on the Business and Financial Update for the Third Quarter of 2023. Thibaut du Fayet, CEO, Eric Soyer, COO/CFO and Pascal Birman, CMO, 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/Blca2c4b7fdc3848098434e7ec14549455>

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/omqc7rs2>

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

UPCOMING FINANCIAL AND SCIENTIFIC EVENTS

- **Investir Day: November 28, 2023 (Paris, France)**
- **Geneva MidCap Event: December 5, 2023 (Geneva, Switzerland)**

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

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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. 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.