PHAXIAM Announces 2023 Full-Year Results and Provides Business Update

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Conference call and webcast (English) on Thursday, March 21, 2024

at 9:30am ET / 2:30pm CET

- **Ongoing clinical efforts boding well to create a global phage-therapy leader in high-value indications**
  - First clinical results of the Phase 1 study in Endocarditis Infections expected in the second half of 2024
  - Plan to launch the 1st global Phase 2 Proof-Of-Concept study in Prosthetic Joint Infections (PJI) in early 2025, leveraging on PhagoDAIR study
- **Compassionate access program continues to gain momentum with the treatment of around 100 patients suffering from Staphylococcus *aureus* and Pseudomonas *aeruginosa* infections**
- **Cash and cash equivalents of €10.5 million ($11.6 million) as of December 31, 2023**

Lyon (France) and Cambridge (MA, US), March 20, 2024, at 6 pm CET – PHAXIAM Therapeutics (Euronext: PHXM; FR0011471135), a biopharmaceutical company developing innovative treatments for severe and resistant bacterial infections, today provides a business and financial update for the fiscal year 2023.

"2023 was a pivotal year for our development, shaped by the creation of PHAXIAM as a pure player in a very promising field of phage therapy." stated **Thibaut du Fayet, Chief Executive Officer of PHAXIAM Therapeutics.** *"In this rapidly evolving therapeutic space, driven by the growing challenges of antimicrobial resistance, our strategic focus is on the most resistant bacterial infections, and primarily those related to* Staphylococcus *aureus. We are therefore pleased to be in close discussions with potential pharma partners and global health authorities, which both confirm the relevance of our strategy. More specifically, the recent feedback received from the FDA and the EMA provide us with clear guidelines for the design of our next global Phase 2 study in Prosthetic Joint Infections. Furthermore, we are about to start the evaluation of our anti-*Staphylococcus *aureus phages in the endocarditis infections in France. Together, with the growing body of clinical data from the Compassionate and Early-Access treatments, we hope that we can successfully execute our clinical plan with anti-*Staphylococcus *aureus phages. The field is clearly moving fast forward, as shown by recent global deals, and we are well positioned to become a leading phage-therapy player able to address the most critical indications for which there is currently no relevant solution, particularly for Prosthetic Joint Infections, for which we are frontrunners."*

MARKET HIGHLIGHTS

Phage therapy sector in a spotlight with recent M&A and refinancing deals

On March 6, 2024, BiomX, a clinical-stage phage-therapy company, announced the acquisition of Adaptive Phage Therapeutics (APT), concurrently with a private placement financing of $50 million, involving several top-tier institutional investors (Deerfield, Orbimed). In the meantime, Armata Pharmaceuticals announced a $35 million refinancing deal.

These important transactions demonstrate the growing attractiveness of phage therapy, where PHAXIAM has a prominent role with its unique and leading positioning in Prosthetic Joint Infections (PJI), as the most advanced Phage therapy player in Europe.

BUSINESS HIGHLIGHTS

a) **Confirmed strategic focus on Phage Therapy in high-value indications with a strong competitive position**

PHAXIAM has been refocusing its clinical development programs in indications of high medical needs, mainly for patients with severe and resistant Staphylococcus *aureus* (*S. Aureus)* infections, often associated with high mortality and budget impact.

This is particularly the case for PJI, where PHAXIAM has a reinforced strategic and leading position. With the signs of clinical activity, we are observing in our compassionate and early-access (AAC, Autorisation d'Accès Compassionnel – the French early access program) patients, and a best-suited approach of local administration of phages allowed in this indication, we strongly believe that PJI is the best option to bring phages as soon as possible as a first indication toward proof-of-concept and registration.

Beyond PJI, as lead indication, PHAXIAM has launched another strategic clinical study (Phase I PK) in Endocarditis infections, reinforcing its ambition to be a leader in innovative therapies to those patients who failed traditional antimicrobial treatments.

b) **Significant progress in Clinical and Regulatory strategy for the S. *aureus* program**

- **Prosthetic Joint Infections (PJI): set for the first global Phase 2 study potentially enabling an Early Access Pathway in Europe**
  - Leveraging on promising activity signals from real-life compassionate treatments and valuable insights from the

current PhagoDAIR pilot study, PHAXIAM is preparing the initiation of the 1st global (EU/US) Phase 2 study for PJI patients (Hip or Knee prosthesis) having an open-surgery debridement (DAIR) in combination with antibiotics.

- PHAXIAM has received positive and consistent feedback from both the FDA (Pre-IND meeting) and the EMA (Scientific Advice) with a view to launching this large-scale study, including the following key points and recommendations:

  - 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 Europe and in the United States;
  - Confirmation of the target population and the Standard of Care to be considered; the exclusion/inclusion criteria allow to target a population approximately 6 times larger compared to the current PhagoDAIR study;
  - Clear and consistent guidelines and expectations in terms of CMC and clinical endpoints.

- PHAXIAM considers (1) accelerating the transitioning of PJI clinical development effort into the new and more ambitious global Phase 2 proof-of-concept study, (2) providing PhagoDAIR pilot study clinical data at the end of 2024.

- The Phase 2 proof-of-concept study is intended to be a multicentric, randomized, double-blind trial and is expected to include 100 patients in Europe and the US. PHAXIAM intends to file a Clinical Trial Application (CTA) with the EMA and the FDA in mid-2024 in view of starting patient enrollment in early 2025.

- Upon a successful completion of this clinical study (2H 2026), PHAXIAM may potentially open an Early Access Pathway for the registration of a first phage therapy treatment for PJI in Europe.

- **Endocarditis Infections (EI): initiate a 2nd clinical study in an indication targeting vital cardiac valves infections**

  - PHAXIAM has obtained approvals from the French ANSM and South-East II-Lyon Ethics Committee to launch a phase 1 study (PK data) in Endocarditis Infections caused by *S. aureus*, to evaluate the safety of intravenous administration (IV) of its anti-S. aureus phages.

  - The study, conducted in 5 French hospitals, is about to start and should enroll 12 patients requiring replacement of an infected heart valve.

  - First clinical results are expected in H2 2024. If positive, these results could allow PHAXIAM to (1) accelerate a clinical development in this indication and to (2) use the IV administration for other indications requiring this administration route, such as bacteriemia.

c) **Robust real-life activity data obtained from compassionate treatments**

In June 2022, the ANSM granted PHAXIAM an AAC (*Autorisation d'Accès Compassionnel*) and, to date, approximately 100 patients have already been treated under this regulatory status for different indications, with a majority in PJI indication.

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.

PHAXIAM has applied for a second AAC regulatory validation, for PJI patients associated with *P. aeruginosa* resistance. This AAC is currently being evaluated by the ANSM for a potential final validation in 2024.

d) **Partnering options**

As part of its strategic development strategy, PHAXIAM is entertaining partnership discussions with pharmaceutical companies, to investigate relevant collaboration options.

e) **Complementary Investigator-sponsored trials**

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

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

Investigator-initiated studies are funded by hospital's clinical research programs and their execution and schedule are entirely under the responsibility of the sponsoring centers.

FY 2023 FINANCIAL RESULTS

Key financial figures for the twelve 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 full-year 2023 include 12 months of ex-Erytech activities and 6 months of ex-Pherecydes activities.

In thousands of euros	**FY2023 12 months**	**FY2022 12 months**
Revenues	—	—
Net income from asset sale		24,351
Other income	1,326	6,647
Operating income	**1,326**	**30,998**
Research and development	(10,910)	(19,907)
General and administrative	(14,076)	(13,887)
Operating expenses	**(24,986)**	**(33,793)**
Operating income (loss)	**(23,660)**	**(2,796)**
Financial income	474	4,453
Financial expenses	(511)	(1,364)
Financial income (loss)	**37**	**3,089**
Income tax	208	(521)
Net loss	**(23,488)**	**(227)**

Operating expenses of €25.0 million in the full-year 2023 were €8.8 million lower (-26%) than in the previous year.

The decrease was driven by the reduction of ex-Erytech R&D expenses, mostly related to the closing of Princeton operations and the termination of clinical development activities, while new ex-Pherecydes development activities were integrated in the P&L as of 2H 2023. Overall, R&D expenses were reduced by €9.0 million (-45%) year-over-year. PHAXIAM's G&A expenses in the full-year 2023 were stable year-over-year (+€0.2 million, i.e. +1%), including one-off expenses related to the merger and integration activities.

Net loss for the full-year 2023 was €23.5 million, compared with a net loss of €0.2 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 December 31, 2023, PHAXIAM had cash and cash equivalents totaling €10.5 million (approximately $11.6 million), compared with €38.8 million as of December 31, 2022. The €28.3 million decrease in cash position during the twelve months of 2023 was the result of a €24.3 million net cash utilization in operating activities and investing activities and €3.7 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 €0.3 million negative currency exchange impact.

The current cash position can fund PHAXIAM's programs and planned operating expenses into September 2024.

EFFECTIVENESS OF VOLUNTARY DELISTING OF AMERICAN DEPOSITARY SHARES FROM NASDAQ STOCK MARKET

On March 11, 2024, PHAXIAM announced that the Company's voluntary delisting of American Depositary Shares ("ADSs") representing its ordinary shares from The Nasdaq Capital Market had become effective. This delisting significantly reduces PHAXIAM's cash utilization and enables the Company to focus its financial resources on key development and value milestones.

The Company remains listed on Euronext Paris as its primary trading market and intends to continue its disclosures in compliance with applicable French financial market regulations.

KEY NEWSFLOW AND MILESTONES EXPECTED OVER THE NEXT 12 MONTHS

- First Patient-In for Phase 1 study in EI (2Q 2024)
- CTA filing for the global Phase 2 study in PJI (3Q 2024)
- Global Phase 2 study in PJI Approval (4Q 2024)
- PhagoDAIR pilot study in PJI clinical data (end 2024)
- Preliminary PK data from the Phase 1 study in EI (2H 2024)
- Launch of the global Phase 2 study in PJI (early 1Q 2025)

FY 2023 CONFERENCE CALL DETAILS

PHAXIAM management will hold a conference call and webcast on **Thursday, March 21, 2024, at 9:30am ET / 2:30pm CET** on the 2023 Full-Year results and Business Update. 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/BIc5665a54501d4da0860376430792d4f5

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/3wxbu7c7

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

FINANCIAL CALENDAR

- Update on business and key financial data for Q1 2024: May 15, 2024 (after market close)
- Annual General Meeting on June 28, 2024

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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. 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.

Attachment

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