Press release

Aelis Farma reports its 2023 annual financial results and confirms its 2024 outlook

- **2023 has been marked by key milestones for the Company's two drug candidates:**
  - **AEF0117: completion of patient recruitment for the phase 2b study with 333 patients in excessive cannabis use disorders**
  - **AEF0217: opening of two new clinical centers in Spain in the second half of the year for the phase 1/2 study in the treatment of cognitive deficits associated with trisomy 21**
- **Strong cash position at €20.2 million as of December 31, 2023, ensuring financial visibility until the end of 2025**

Bordeaux, April 2, 2024 – 5:45 p.m. CEST – Aelis Farma (ISIN: FR0014007ZB4 – Ticker: AELIS), a clinical-stage biopharmaceutical company specialized in the development of treatments for brain diseases, today announces its full year results for the year to December 31, 2023.

Pier Vincenzo Piazza, CEO of Aelis Farma, stated: *"The year 2023 was marked by significant progress for our two drug candidates, AEF0117 and AEF0217, demonstrating our ability to deliver on the development milestones announced to the market since our IPO in 2022. For AEF0117, several key achievements stand out, such as the publication in Nature Medicine presenting the molecule discovery to preliminary phase 2a efficacy results. The positive recommendation from the Data Safety Monitoring Board halfway through the phase 2b study, and the completion of patient recruitment for this study with 333 patients. Furthermore, the positive results obtained from all regulatory non-clinical studies will enable a rapid transition to phase 3 upon success of the phase 2b study. For AEF0217, the current phase 1/2 study assessing the safety and tolerability of the compound in individuals with Down syndrome will pave the way for a multicenter phase 2 study in several European countries. This study aims to assess the efficacy of AEF0217 in treating cognitive deficits associated with Down syndrome is planned to start late 2024/early 2025. We are also making progress in identifying new therapeutic indications for AEF0217. Finally, our proprietary platform has enabled us to identify several CB_1-SSis with new properties targeting a broader range of diseases involving the CB_1 receptor. We have also appointed Arsène Guekam as Chief Corporate Development Officer, bringing his in-depth knowledge of financial markets and sector trends. For the year 2024, our main objective is to deliver on the announced clinical study timelines for our two drug-candidates. We also aim to initiate the pre-clinical development of a third CB_1-SSi by the end of 2024. Thanks to the expertise and dedication of our team, we are confident to achieve these goals and progress towards becoming a leading player in the field of brain disease treatments."*

Full-year results 2023 (IFRS)

Simplified income statement1 (in €K)	2023	2022
Revenue from ordinary activities	12,358	8,364
Research and development costs	(16,212)	(13,792)
General and administrative expenses and other operating income and expenses	(2,607)	(3,096)
Operating income	**(6,461)**	**(8,525)**
Financial result	1,386	(5,762)
Income taxes	(3)	(1)
Net income (loss)	**(5,078)**	**(14,288)**

For the full year 2023, Aelis Farma recorded revenue from ordinary activities of €12.4 million, including:

- €9.1 million corresponding to the recognition, in accordance with IFRS 15, of the share of revenue related to the license option agreement with Indivior PLC, a leading group in the treatment of addictions, for the use of AEF0117 as a treatment of cannabis use disorders. The balance of the lump-sum payment received in 2021 and yet to be recognized over the residual term of the option amounts to €2.7 million. The revenue recognized for the fiscal year 2023, based on the progression of costs for the phase 2b of AEF0117, has increased by €5.2 million compared to 2022. This increase is attributed to the increased activity of the phase 2b clinical study and the completion of its recruitment.
- €3.3 million in other income from ordinary activities, comprising the Research Tax Credit (€1,597,000), operating subsidies (€1,010,000) and studies re-invoiced without margin (€696,000) related to Aelis Farma's research programs. The decrease in other income compared to the previous fiscal year (-€1.3 million) is explained by the reduction in Research Tax Credit, linked to fewer eligible activities in 2023, given the studies carried out in the United States in particular, and the lesser impact of grants recognized in income in 2023.

Research and development costs

In €K	12/31/2023	12/31/2022
Raw materials, other purchases, and external expenses	(14,047)	(11,574)
Personnel costs	(2,002)	(2,052)
Intellectual property	(163)	(166)
Research and development costs	**(16,212)**	**(13,792)**

The increase in research and development expenses (+18%) reflects significant progress in the clinical and non-clinical development programs, observed particularly in the second half of 2023, of our drug candidates AEF0117 and AEF0217, as well as the growth of activities of our proprietary discovery platform.

General and administrative expenses

In €K	12/31/2023	12/31/2022
Other purchases and external charges	(1,097)	(1,670)
Staff costs	(1,510)	(1,426)
General and administrative expenses	**(2,607)**	**(3,096)**

[1] The annual financial statements were approved by the Board of Directors on April 2,2024. Review procedures have been performed on these financial statements. The statutory auditors' review report is currently being issued.

General and administrative expenses as of December 31, 2023 amounted to €2,607,000, down €489,000 compared to the previous year. This decrease mainly relates to other purchases and external expenses, which included in 2022 costs relating to the Company's IPO not charged to the share premium.

The operating result recorded on December 31, 2023 was therefore a loss of €6,461,000, compared with a loss of €8,525,000 at December 31, 2022. This change was mainly due to:

- the progress and completion of recruitment for the phase 2b study of AEF0117 during the fiscal year 2023;
- the speeding up of recruitments and expansion of the clinical centers for the phase 1/2 study with AEF0217, primarily in the second half of 2023;
- the continuation of development activities for the pharmaceutical production (CMC) of AEF0117 for phase 3 and of AEF0217 for phase 2, as well as other regulatory clinical and non-clinical studies required for AEF0117 to enter phase 3;
- the pace of revenue recognition related to the license option agreement with Indivior PLC, based on the advancement of AEF0117 phase 2b costs.

Financial income showed a profit of €1,386,000 as of December 31, 2023, compared with a loss of €5,762,000 at December 31, 2022. This mainly comprises the financial income recognized at the moment of the payment of R&D charges, which were self-hedged in dollars. To be noted, as of December 31, 2022, the non-cash financial expense associated with the conversion of convertible bonds on the date of Aelis Farma's IPO was also recognized.

The net result was a loss of €5,078,000 for the full year 2023, compared with a loss of €14,288,000 for the same period of 2022.

Cash flow

Cash flow (in €K)	12/31/2023	12/31/2022
Cash flow from operating activities	**(12,959)**	**(13,051)**
Net cash flow from investing activities	**(88)**	**(137)**
Net cash flow from financing activities	**(967)**	**22,149**
Impact of exchange rate changes	(170)	723
Change in cash and cash equivalents	**(14,184)**	**9,684**
Opening cash position	34,396	24,710
Closing cash position	20,211	34,396

Financial structure

Financial structure (in €K)		12/31/2023	12/31/2022
Liquid assets	**a**	**20,230**	**34,396**
Gross financial debt	**b**	**(4,040)**	**(3,823)**
Net cash position	**a+b**	**16,190**	**30,572**

The year 2022 was marked by the capital increase carried out in connection with the Company's IPO, generating a net financing cash flow of €22.1 million. In 2023, in addition to the repayment of the Company's debt maturities (-€1 million) and payments to the liquidity contract (€0.5 million), this cash flow includes interest received on financial investments (€0.5 million).

Aelis Farma's financial structure remains robust at the end of the full year 2023, with a net cash position of €16,190,000. The Company's cash consumption is in line with its forecasts and the progress of its research and development program.

Aelis Farma believes that its current cash position will enable it to finance its development, in line with the strategy presented during the IPO, until at least the end of 2025.

Highlights of the full year 2023

Publication of the first article on AEF0117 in *Nature Medicine*

In June 2023, the prestigious scientific journal *Nature Medicine* published the first article describing the new pharmacological class discovered by Aelis Farma, the CB_1-SSi, and the discovery and development of the first of these compounds, AEF0117, including the positive data from a phase 2a clinical trial in volunteers with cannabis addiction.

This article provides a scientific validation of the quality of the work carried out and the potential of AEF0117, and more generally of the new CB_1-SSi pharmacological class.

Favorable review by a DSMB (Data and Safety Monitoring Board) in the phase 2b study of AEF0117

The conclusions of a DSMB, the committee of independent experts to monitor the trial, were released at the end of the first semester of 2023. Safety and tolerability data from the initial 115 patients treated with AEF0117 for at least 4 weeks were assessed, and no serious adverse or significant treatment-related events were reported by the committee, which recommended continuing the study without modification to the protocol.

Positive results from regulatory non-clinical studies of AEF0117

AEF0117 demonstrated a highly favorable therapeutic index, over 13,000 times greater than the active dose, in *in vivo* toxicological studies including a chronic oral toxicity study (6 months in rats and 9 months in dogs), allowing for chronic treatments without duration restriction in humans. Additionally, reproductive toxicology studies demonstrated that AEF0117 does not alter embryonic and embryofetal development. With the successful early completion of additional non-clinical and current clinical development complementary to toxicity studies, AEF0117 will be ready to enter phase 3 clinical trials for the treatment of cannabis addiction upon successful completion of the present phase 2b clinical trial and regulatory approval of the phase 3 protocol.

Completion of recruitment for the phase 2b clinical study with AEF0117 for the treatment of cannabis addiction

Under the coordination of Professor Frances Levin from Columbia University (New York), recruitment and randomization of the 333 patients for the phase 2b trial of AEF0117 at 11 clinical centers in the United States were completed in December 2023. The Company expects to announce the results of the study after 2024 summer break.

Strengthening of the recruitment capacity for the phase 1/2 study of AEF0217 with the opening of two clinical centers

The transition of the phase 1/2 study to a multicenter trial has been completed with the aim of significantly increase the recruitment of subjects of this initial safety evaluation of AEF0217 in people with Down Syndrome. In addition, this study and the multiple encounters with Down syndrome family association is anticipating the groundwork for the establishment of a network capable of swiftly executing the future phase 2 study, evaluating the efficacy of AEF0217 for the treatment of cognitive deficits associated with Down syndrome. This study is expected to start in late 2024/early 2025.

Strategy & outlook

Develop AEF0117 to address the adverse effects of excessive cannabis use

Aelis Farma expects to announce the efficacy results of the phase 2b study with AEF0117 after 2024 summer break. Following these results, Indivior could exercise its licensing option, triggering a license fee payment of $100 million, and up to an additional $340 million in milestone payments contingent upon the achievement of development, regulatory, and commercial milestones, as well as royalties on net sales of AEF0117 ranging from 12% to 20%.

Aelis Farma aims also to finalize in 2024 additional clinical studies required for the entry into phase 3 of AEF0117. These studies, combined with positive results from the phase 2b trial and the positive results already obtained in regulatory non-clinical studies, would allow the start of phase 3 trials, upon approval by regulatory agencies of their clinical protocols.

Develop AEF0217 to address various cognitive deficits, including those associated with Down syndrome

The primary objective for 2024 is to successfully complete the phase 1/2 study and the initiation of the phase 2 study. The phase 1/2 study aims primarily to analyze the safety and pharmacokinetics of AEF0217 in Down syndrome people. The obtention of convincing safety and pharmacokinetic results would pave the way for a multicenter phase 2 study, expected to start late 2024/early 2025, that will aim to demonstrate the therapeutic effects of AEF0217 for the treatment of cognitive deficits associated with Down syndrome. The development of AEF0217 in Down syndrome benefits from a grant of €6 million of the European community (Project ICOD No. 899986).

In 2024, the Company also aims to strength the knowledge on the additional therapeutic indications of AEF0217 which include the cognitive deficits observed in genetic forms of autism spectrum disorders, during aging and in neuropsychiatric conditions such as schizophrenia and Parkinson's disease.

Identifying new drug candidates

Given the involvement of the CB_1 receptor in numerous pathologies and leveraging its diversified and exclusive library of CB_1-SSi, Aelis Farma continues to characterize new CB_1-SSi candidates which aim to treat other CB_1 receptor-dependent disorders.

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About AELIS FARMA

Founded in Bordeaux in 2013, Aelis Farma is a biopharmaceutical company that is developing a new class of drugs, the Signaling-Specific inhibitors of the CB_1 receptor of the endocannabinoid system (CB_1-SSi). CB_1-SSi have been developed by Aelis Farma based on the discovery of a natural regulatory mechanism of CB_1 hyperactivity made by the team led by Dr. Pier Vincenzo Piazza, the Company's CEO, when he was the director of the Neurocentre Magendie of the INSERM in Bordeaux. By mimicking this natural mechanism, CB_1-SSi appear to selectively inhibit the disease-related activity of the CB_1 receptor without disrupting its normal physiological activity. CB_1-SSi have consequently the potential to provide new safe treatments for several brain diseases.

Aelis Farma is currently developing two first-in-class clinical-stage drug candidates: AEF0117 for the treatment of cannabis use disorder (CUD), currently being tested in a phase 2b study in the United States; and AEF0217 for cognitive disorders, including those of Down Syndrome (Trisomy 21), currently in a phase 1/2 study in Spain in people with Down syndrome. The Company also has a portfolio of new innovative CB_1-SSi for the treatment of other disorders associated with a dysregulation of the activity of the CB_1 receptor.

Aelis Farma draws on the talents of more than 25 highly qualified employees.

For more information, visit www.aelisfarma.com and follow us on LinkedIn and Twitter.

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Disclaimer

Forward-looking statements

Some information contained in this press release are forward-looking statements, not historical data. These forward-looking statements are based on current beliefs, expectations, and assumptions, including, but not limited to, assumptions about Aelis Farma's current and future strategy and the environment in which Aelis Farma operates. They involve known and unknown risks, uncertainties, and other factors, which may cause actual results, performance, or achievements, or industry results or other events, to differ materially from those described or implied by such forward-looking statements. These risks and uncertainties include those set out and described in detail in Chapter 3 "Risk Factors" of Aelis Farma's Universal Registration Document approved by the Autorité des Marchés Financiers on April 26, 2023, under number R.23-018.

These forward-looking statements are made only as of the date of this press release and Aelis Farma expressly disclaims any obligation or undertaking to release any updates or corrections to the forward-looking statements included in this press release to reflect any change in expectations or events, conditions, or circumstances on which any such forward-looking statement is based. Forward-looking information and statements are not guarantees of future performance and are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond Aelis Farma's control. Actual results could differ materially from those described in, or implied or projected by, forward-looking information and statements.