

Aelis Farma reports its 2024 annual financial results and confirms its 2025 outlook

2024 has been marked by several significant events:

- **The achievement of key milestones for the Company's two drug candidates:**
 - AEF0117: announcement of the results of the Phase 2b clinical study in cannabis use disorders
 - AEF0217: announcement of results from the Phase 1/2 clinical study in the treatment of cognitive deficits in trisomy 21.
- **These results confirm the safety and pharmacological activity of the new CB₁-SSi class in humans.**
- **Expansion of the capabilities of the proprietary platform to intensify and accelerate the screening and identification of new CB₁-SSi molecules.**
- **Solid cash position of €14 million as of December 31, 2024, strengthened by a fundraising in July 2024 and ensuring financial visibility until the end of 2026.**

Bordeaux, April 1st, 2025 – 6:00 pm CEST – Aelis Farma (ISIN: FR0014007ZB4 – Ticker: AELIS), a clinical-stage biopharmaceutical company specializing in the development of treatments for brain and peripheral diseases involving the CB₁ receptor, today announces its full year results for the year ended December 31, 2024.

Pier Vincenzo Piazza, CEO of Aelis Farma, stated: *“The year 2024 was marked by significant advances in the clinical developments of our two drug candidates, AEF0117 and AEF0217, confirming the therapeutic activity of CB₁-SSi in humans. For AEF0117, although the Phase 2b study in cannabis addiction (CUD) did not meet its primary endpoint, the preliminary and final results demonstrated that AEF0117 is capable of statistically significantly reduce cannabis consumption in some patients. This study also confirmed the excellent safety and tolerability of AEF0117. For AEF0217, the results of the Phase 1/2 study in people with Down syndrome demonstrated adequate absorption, as well as excellent safety and tolerability of the compound in this more fragile population. AEF0217 also statistically significantly normalized the excessive brain activity observed in people with Down syndrome when performing a cognitive task, and improved adaptive behaviors in the areas of communication, daily tasks and social interactions. Finally, our proprietary platform has enabled us to identify several CB₁-SSi with novel functional properties that allow us to target a wider range of diseases involving the CB₁ receptor, in particular obesity, metabolic diseases and fibrosis. For the year 2025, our first objective is to start the studies already fully funded, namely a Phase 2b clinical study with AEF0217 in Down syndrome and animal testing of our new compounds addressing obesity and metabolic disorders. We also aim to develop industrial partnerships in order to further the development of AEF0117 and to fully exploit AEF0217 numerous therapeutic indications, which extend well beyond the cognitive deficits associated with Down syndrome. Backed by the skills of our teams, we are confident of achieving these objectives, and of becoming a leading player in the development of innovative treatments for cerebral and peripheral diseases.”*

Full-year results 2024 (IFRS)

Simplified income statement ¹ (in €K)	2024	2023
Revenue from ordinary activities	5,562	12,358
Research and development costs	(9,942)	(16,212)
General and administrative expenses	(3,355)	(2,607)
Operating income	(7,735)	(6,461)
Financial result	287	1,386
Income taxes	(8)	(3)
Net income (loss)	(7,456)	(5,078)

During the year ended December 31, 2024, the Company recorded income from ordinary activities of €5.6 million, including:

- €2.7 million corresponding to the recognition as sales, in accordance with IFRS 15, of the residual share of revenues associated with the license option agreement with Indivior PLC for AEF0117 in cannabis use disorders. At the closing of the 2024 financial year, all the revenue associated with the lump-sum payment received in 2021 has been recognized, representing a cumulative amount of €24.6m compared with €21.9m at December 31, 2023.
- €2.9 million of other income from ordinary activities, comprising the Research Tax Credit (€1,663,000), operating subsidies (€419,000) and studies re-invoiced without margin (€802,000) related to Aelis Farma's research programs. Other income was down €0.4 million on the previous year, due in particular to the lower proportion of exploration grants charged to the income statement in 2024 (-€0.6 million), offset by an increase in Research Tax Credit and other income (+€0.2 million).

Research and development costs

In K€	12/31/2024	12/31/2023
Raw materials, other purchases, and external expenses	(7,161)	(14,047)
Personnel costs	(2,370)	(2,002)
Intellectual property	(410)	(163)
Research and development costs	(9,942)	(16,212)

The decline in R&D expenses (-39%) is due in particular to the high level of expenses incurred in 2023 for AEF0117, which were linked in particular to Phase 2b clinical study, for which recruitment was completed in December 2023, and to complementary non-clinical developments. R&D expenses incurred in 2024 cover in particular:

- The completion of the AEF0117 Phase 2b and AEF0217 Phase 1/2 clinical trial programs;
- Non-clinical activities in preparation for AEF0217 Phase 2b;
- Growth in the activities of the proprietary research platform; and
- The costs of granting two patents in Europe.

¹ The annual financial statements were approved by the Board of Directors on April 1, 2025. Audit procedures have been completed on these financial statements. The statutory auditors' certification report is currently being issued.

General and administrative expenses

In K€	12/31/2024	12/31/2023
Other purchases and external charges	(1,304)	(1,097)
Staff costs	(2,051)	(1,510)
General and administrative expenses	(3,355)	(2,607)

General and administrative expenses at December 31, 2024, totaled €3,355,000, up €748,000 on the previous year. This increase is mainly due to personnel costs, and more specifically to the impact of a full-year increase in headcount.

Operating income for the year ended December 31, 2024, therefore showed a loss of €7,735,000, compared with a loss of €6,461,000 for the year ended December 31, 2023. This change is mainly due to:

- the completion of the AEF0117 Phase 2b study and the recognition of residual sales linked to the license option agreement with Indivior PLC;
- the continuation of other regulatory clinical and non-clinical studies, initiated in 2023, and necessary in view of AEF0117's entry into Phase 3;
- the finalization of the Phase 1/2 study with AEF0217 and preparation for the Phase 2b study in the treatment of cognitive deficits associated with trisomy 21, including regulatory non-clinical activities; and
- intensification of the proprietary platform's activities relating to the identification and characterization of new compounds.

Net financial income amounted to €287,000 at December 31, 2024, compared with €1,386,000 at December 31, 2023. In 2024, it mainly comprised financial income from cash investments. It should be noted that in 2023, it was made up of financial income recognized at the time of settlement of Research and Development operations, which were self-hedged in dollars.

Net income was a loss of €7,456,000 in 2024, compared with a loss of €5,078,000 in the previous year.

Cash flow

Cash flow (in K€)	12/31/2024	12/31/2023
Cash flow from operating activities	(11,831)	(12,959)
Net cash flow from investing activities	(190)	(88)
Net cash flow from financing activities	5,808	(967)
Impact of exchange rate changes	53	(170)
Change in cash and cash equivalents	(6,160)	(14,184)
Opening cash position	20,211	34,396
Closing cash position	14,051	20,211

Financial structure

Structure financière (in K€)		12/31/2024	12/31/2023
Liquid assets	a	14,051	20,230
Gross financial debt	b	(6,084)	(4,040)
Net cash position	a+b	7,967	16,190

The year 2024 was marked on the one hand by the capital increase for a gross amount of €4.5 million carried out in July 2024, and on the other hand by the granting of two loans for a total amount of €3 million, thus generating a net financing flow of €5.8 million (-€0.9 million in 2023).

As a result, Aelis Farma's financial structure remains solid at year-end 2024, with a cash position of €14,051,000. The Company's cash burn 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 until at least the end of 2026.

Highlights of the full year 2024

Transfer of the screening laboratory for the identification of new CB₁-SSi

In April 2024, Aelis Farma transferred its discovery research teams to a new laboratory at the IECB (Institut Européen de Chimie et de Biologie) in Pessac (Bordeaux).

The new 200 sqm laboratory is equipped with state-of-the-art technologies and proprietary screening platforms, enabling Aelis Farma to accelerate its drug discovery process. With these enhanced capabilities, Aelis Farma will be able to conduct in-depth research, discovering promising new molecular entities and identifying their mechanism of action for the treatment of various diseases.

Successful capital increase of €4.5 million

At the end of July 2024, Aelis Farma successfully completed a €4.5 million capital increase, which enabled the Company to expand its shareholder base by including new high-quality investors, and to accelerate the development of the new CB₁-SSi families produced by its platform, with the strategic priority of broadening its therapeutic targets. These include, in particular, a treatment of obesity-related metabolic diseases, in which the CB₁ receptor, the target of the Company's drug candidates, is strongly implicated. It is important to recall that the drug candidates developed by Aelis Farma belong to the same pharmacological class of CB₁-SSi but have distinct functional effects which enable them to target different pathologies.

Publication of preliminary analyses of Phase 2b results with AEF0117 in participants suffering from cannabis addiction (cannabis use disorders - CUD)

In September 2024, Aelis Farma released preliminary results from the Phase 2b trial with AEF0117. AEF0117 is the first of a new pharmacological class named the Signalling Specific inhibitors of the CB₁ receptor of the endocannabinoid system (CB₁-SSi). Although AEF0117 did not show a statistically significant effect on the primary endpoint, encouraging trends were observed, demonstrating AEF0117 pharmacological activity and safety. After analysis of the preliminary results, Indivior PLC has communicated that it did not intend to exercise the option it had acquired for a global licence of AEF0117.

Aelis Farma has pursued its quality control process and conducted further analysis of the Phase 2b data.

Publication of Phase 1/2 results with AEF0217 in young adults with trisomy 21

As described in the press release of November 18, 2024, the results of the Phase 1/2 study with AEF0217 in young adults with trisomy 21 showed that:

- AEF0217 was well tolerated, and no safety issues were identified, confirming that the drug candidate can be used without identified risks, in a more fragile population such as young adults with Down syndrome.

- After four weeks of treatment, AEF0217 statistically significantly improved several important adaptive behaviors in the areas of communication, daily living skills and social interactions, as measured by the benchmark Vineland Adaptive Behavior Scale (VABS).
- These improvements were associated with a trend towards increased cognitive flexibility, as measured by the NIH-Toolbox Cognitive Battery.
- Statistically significant changes in electroencephalographic (EEG) features indicating a reduction in the effort required to perform a working memory task, as well as EEG markers of target engagement, were also observed.

These positive efficacy and safety results will enable the Company to launch a multi-center Phase 2b study in the second half of 2025.

Strategy & outlook

On the strength of its solid financial situation, Aelis Farma intends to pursue the development of its various assets and reach the next stages of value creation.

Publication of final analyses of Phase 2b results with AEF0117

Following the publication of the preliminary results of this study in September 2024, the final analyses were published on March 26, 2025. These analyses show that:

- AEF0117 is well tolerated and without the adverse effects of CB₁ receptor antagonists. The highest dose of AEF0117 (1mg) non-statistically significantly increased the proportion of responders (+100% vs. placebo) for the primary endpoint (cannabis use ≤ 1 day per week) and almost statistically significantly reduced (-16% vs. placebo; P=0.077) the number of days of cannabis use per week.
- In the subgroup of patients with a strong motivation to stop using cannabis, AEF0117 had a greater effect on the primary endpoint (+228% vs. placebo), on the number of days of cannabis use per week (-55% vs. placebo; P=0.038) and on the amount of money spent on cannabis per day of use (-76% vs. placebo P=0.029).
- As already observed in Phase 2a, these data confirm, that AEF0117 is pharmacologically active, and provide further validation of the activity of the new class of drugs developed by Aelis Farma, "Specific CB₁ Receptor Signaling Inhibitors (CB₁-SSi)".

These new results will be the ground to engage in new partnership discussions, allowing to move forward the development of AEF0117.

Launch of a multicenter Phase 2b trial with AEF0217 to treat cognitive deficits associated with trisomy 21

The results of the Phase 1/2 study in people with trisomy 21, reported in November 2024, pave the way for a multicenter Phase 2b study, scheduled to start in the second half of 2025. This study, which will include a total of 180 participants in around 10 clinical centers across France, Italy and Spain, will

aim to confirm the therapeutic effects of AEF0217 for the treatment of cognitive deficits associated with Down syndrome.

Further development of AEF0217 to treat other cognitive deficits, including those associated with Down syndrome

In 2024, Aelis Farma initiated additional preclinical studies to better determine the potential therapeutic indications for AEF0217 in the vast field of cognitive deficits. These studies are due to be completed in 2025 and will define the possibility of initiating clinical trials in new indications.

Developing new drug candidates on the Company's platform

Thanks to its diversified and proprietary CB₁-SSi library and screening platform, Aelis Farma has discovered functionally distinct families of compounds targeting the CB₁ receptor that could address a broad spectrum of diseases associated with receptor dysregulation. Some of these molecules have entered development and are undergoing early toxicity and pharmacokinetic testing. They will then be tested in mouse models of obesity and associated metabolic diseases.

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 CB₁ receptor of the endocannabinoid system (CB₁-SSi). CB₁-SSi have been developed by Aelis Farma based on the discovery of a natural regulatory mechanism of CB₁ 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 INSERM in Bordeaux. By mimicking this natural mechanism, CB₁-SSi appear to selectively inhibit the disease-related activity of the CB₁ receptor without disrupting its normal physiological activity. CB₁-SSi have consequently the potential to provide new safe treatments for several brain and peripheral organ diseases.

Aelis Farma currently has two first-in-class clinical-stage drug candidates. AEF0117 for the treatment of cannabis use disorders (CUD), that has shown to be able to decrease cannabis use across two studies. AEF0217 for cognitive disorders, which has shown in a Phase 1/2 to be safe and able to improve adaptive behaviour in young adults with Down syndrome (Trisomy 21). The clinical results obtained with these 2 molecules have confirmed the pharmacological activity of CB₁-SSi in humans. The Company also has a portfolio of new innovative CB₁-SSi for the treatment of other disorders associated with a dysregulation of the activity of the CB₁ receptor, including diseases involving peripheral organs, such as obesity and related metabolic conditions. The different drugs developed by the company belong to the same general pharmacological class, the CB₁-SSi, but have distinct functional effects allowing to target different types of dysregulations of the CB₁ receptor and guaranteeing that the different compounds are not substitutable one with the others.

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

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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.