Press release

Aelis Farma reports 2025 half-year financial results and presents progress and development outlook

The first half of 2025 was marked by:

- **The publication of the final analysis of the pioneering Phase 2b clinical trial in cannabis use disorders (CUD) with the CB_1-SSi AEF0117, which further validated the new pharmacological class of CB_1-SSi by confirming the compound's safety and its ability to reduce cannabis consumption, although the primary endpoint was not reached.**

- **Significant progress in preparing the multicentre Phase 2b study with AEF0217 for the treatment of behavioural deficits associated with Down syndrome, which is scheduled to start in the second half of 2025, in line with the announced plan.**

- **Rigorous cost management, resulting in a solid cash position of €10.8 million as of 30 June 2025, providing financial visibility beyond 2026, which could be further extended through additional non-dilutive funding.**

Bordeaux, September 22, 2025 – 7:00 am CEST – Aelis Farma (ISIN: FR0014007ZB4 – Ticker: AELIS), a clinical-stage biopharmaceutical company specialising in the development of treatments for brain and peripheral diseases involving the CB_1 receptor, today announces its financial results for the first half of 2025 and provides a business update.

Pier Vincenzo Piazza, CEO of Aelis Farma, stated: *"The first half of 2025 was characterized by important achievements in the development of our drug candidates. The final analysis of the Phase 2b study with AEF0117 confirmed its ability to significantly reduce cannabis consumption in certain patients, although the primary endpoint was not met. With an in-depth understanding of AEF0117's effects, we remain fully committed to identifying the best partnership or regulatory pathways to advance its development. For AEF0217, following the successful Phase 1/2 study in individuals with Down syndrome, we are preparing an international multicentre Phase 2b study aimed at confirming AEF0217's potential to improve behavioural deficits in this population. This study is expected to begin in the second half of 2025, as planned. At the same time, our research platform has enabled early development and preclinical proof-of-concept of a new family of CB_1-SSi with distinct and complementary characteristics to AEF0117 and AEF0217. These new molecules target obesity and associated metabolic disorders, as well as other CB_1-related brain diseases. Thanks to strict resource management, we currently have a solid cash position providing financial visibility beyond 2026, which we intend to extend through additional non-dilutive funding. We have also launched a very active business development strategy to accelerate the progress of our drug candidates and to strengthen the Company's financial position. We approach the coming months with a clear roadmap and the ambition to reach new milestones towards establishing Aelis Farma as a leading player in the development of innovative treatments for brain and peripheral diseases."*

Half-year results 2025 (IFRS)

Simplified income statement[1] (in €K)	06/30/2025	06/30/2024
Revenue from ordinary activities	895	4,124
Research and development costs	(3,702)	(6,115)
General and administrative expenses	(1,339)	(1,673)
Operating income	**(4,145)**	**(3,665)**
Financial result	(174)	83
Income taxes	(4)	0
Net income (loss)	**(4,323)**	**(3,583)**

In the first half of 2025, Aelis Farma recorded revenue from ordinary activities of €0.9 million, corresponding to other income from ordinary activities (compared to €1.9 million as of June 30, 2024), comprising the French Research Tax Credit (€565,000), operating subsidies and studies charged back (€329,000) related to Aelis Farma's research programs.

It should be noted that in the first half of 2024, Aelis Farma recorded revenue of €2.2 million corresponding to the recognition of part of the income from the license option agreement with Indivior PLC. The remaining balance of the lump-sum payment, which amounted to €0.4 million, was recognized in the income statement in the second half of 2024.

Research and development costs

In €K	06/30/2025	06/30/2024
Raw materials, other purchases, and external expenses	(2,490)	(4,857)
Personnel costs	(1,101)	(1,041)
Intellectual property	(111)	(217)
Research and development costs	**(3,702)**	**(6,115)**

Research and development (R&D) costs decreased compared to June 30, 2024, mainly due to the completion of the Phase 2b clinical study for AEF0117 and the Phase 1/2 study for AEF0217 at the end of 2024.

R&D expenses incurred in the first half of 2025 mainly covered:

- preparatory activities for the AEF0217 Phase 2b trial (drug product manufacturing and clinical trial set-up);
- expansion of activities on the proprietary research platform; and
- patent maintenance costs.

[1] The interim financial statements were approved by the Board of Directors on September 19, 2025. Limited review procedures have been performed on these financial statements. The statutory auditors' limited review report is currently being issued.

General and administrative expenses

In €K	06/30/2025	06/30/2024
Other purchases and external charges	(682)	(639)
Staff costs	(657)	(1,034)
General and administrative expenses	**(1,339)**	**(1,673)**

General and administrative expenses at June 30, 2025, totaled €1,339,000, compared to €1,673,000 at June 30, 2024. This decrease is mainly due to lower personnel costs, reflecting a reduced allocation of management time to administrative activities and a decrease in expenses related to the valuation of stock option (BSA and BSPCE) plans under IFRS 2.

Operating income therefore showed a loss of €4,145,000 at June 30, 2025, compared with a loss of €3,665,000 at June 30, 2024.

Financial income showed a loss of €174,000 at June 30, 2025, compared with a gain of €83,000 at June 30, 2024. It mainly includes income from cash investments (€104,000) and a foreign exchange loss of €151,000. At June 30, 2024, the financial mainly comprised income from cash investments.

For the first half of 2025, net income was a loss of €4,323,000 in 2024, compared with a loss of €3,583,000 for the same period in 2024.

Cash flow

Cash flow (in €K)	06/30/2025	06/30/2024
Cash flow from operating activities	**(3,883)**	**(8,177)**
Net cash flow from investing activities	**(6)**	**(165)**
Net cash flow from financing activities	**771**	**719**
Impact of exchange rate changes	(151)	(4)
Change in cash and cash equivalents	**(3,269)**	**(7,626)**
Opening cash position	14,051	20,211
Closing cash position	10,791	12,585

Financial structure

Financial structure (in €K)		06/30/2025	12/31/2024
Liquid assets	**a**	**10,791**	**14,051**
Gross financial debt	**b**	**(6,889)**	**(6,084)**
Net cash position	**a+b**	**3,897**	**7,967**

Aelis Farma's financial structure remains solid, reflecting rigorous cost management and resulting in a cash position of €10.8 million as of 30, 2025.

During the period, the Company also secured a €1.5 million loan from its new financial partner, Caisse d'Epargne Nouvelle-Aquitaine.

With this financial foundation, Aelis Farma believes that its current cash position enables it to execute its R&D program, with financial visibility extending beyond 2026, a horizon that could be further extended through additional non-dilutive funding.

Highlights of the first half of 2025, outlook & strategy

Publication of final analyses of Phase 2b results with AEF0117

The final results of the Phase 2b clinical study with AEF0117 in cannabis use disorders were published on March 26, 2025. These analyses show that AEF0117 is well tolerated, does not present the adverse effects commonly observed with CB_1 receptor antagonists, and is pharmacologically active, as:

- The highest dose of AEF0117 (1mg) induced a non-statistically significant increase in the proportion of responders (+100% vs. placebo) for the primary endpoint (cannabis use ≤1 day per week), and reduced close to statistical significance the number of days of cannabis use per week (-16% vs. placebo; P=0.077).
- In the subgroup of patients highly motivated 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 per day on cannabis (-76% vs. placebo; P=0.029).

These findings provide further validation of the pharmacological activity of the new drug class developed by Aelis Farma, "Signaling-Specific Inhibitors of the CB_1 receptor (CB_1-SSi)", and will serve as the ground for initiating new partnership discussions to move forward the development of AEF0117.

Preparation of an international Phase 2b trial with AEF0217 in Down syndrome (trisomy 21)

Following the successful Phase 1/2 study, which showed that AEF0217 can improve adaptive behaviour and certain brain activities in individuals with Down syndrome, the Company devoted substantial resources to preparing a Phase 2b trial aimed at confirming these beneficial effects on adaptive behaviour. This international study, conducted across approximately 10 clinical centers in France, Spain, and Italy, is scheduled to start in the second half of 2025.

The clinical centers have already been selected and validated by the Company. The study protocol and the Paediatric Investigation Plan (PIP) are in the final stages of validation by the European Medicines Agency (EMA). Several meetings were also held with family associations in different countries, as well as at the European Parliament on World Down Syndrome Day (March 21, 2025).

Development of new drug candidates on the Company's platform

Thanks to its diversified and proprietary CB_1-SSi library and screening platform, Aelis Farma has discovered several families of compounds with distinct functional properties targeting the CB_1 receptor, with potential to treat a broad spectrum of diseases associated with CB_1 dysregulation. Some of these molecules have already entered early development (toxicology, formulation, and pharmacokinetic studies) and preclinical proof-of-concept (animal efficacy studies). These new molecules primarily target obesity and associated metabolic diseases, in which CB_1 hyperactivity plays a major role, but could also be developed for other CB_1-related brain diseases.

Acceleration of business development activities

In the first half of 2025, Aelis Farma signed a consultancy agreement with Staatz Business Development & Strategy, a firm led by its founder Irina Staatz, who also serves as a member of Aelis Farma's Board of Directors. The purpose of this collaboration is to support and intensify the management team's efforts in identifying partners, by increasing the Company's presence at key industry conferences and initiating strategic discussions that could lead to pharmaceutical partnerships for Aelis Farma's drug candidates. Establishing partnerships for AEF0117 and AEF0217 remains one of the Company's core strategic priorities to accelerate the development of these compounds, secure additional funding, and strengthen its financial position.

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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 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 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 CB_1-SSi in humans. 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, 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 CB_1-SSi, but have distinct functional effects allowing to target different types of dysregulations of the CB_1 receptor and guaranteeing that the different compounds are not substitutable one with the others.

Aelis Farma draws on the talents of more than 20 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 is 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, 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 24, 2024, under number R.24-004.

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.