Press release

Aelis Farma reports its 2025 annual financial results and confirms its 2026 outlook

2025 has been marked by several significant events:

- **The achievement of key milestones for the Company's two drug candidates:**
  - AEF0117: announcement of the final results of the Phase 2b clinical study in cannabis use disorders
  - AEF0217: obtention of regulatory approvals and successful start of the recruitment of the Phase 2b clinical study for the treatment of behavioral and cognitive impairments of people with Down syndrome.
- **Solid cash position of €9.1 million as of December 31, 2025, strengthened by new non-dilutive fundings and ensuring financial visibility until the beginning of 2028.**

Bordeaux, France, March 30, 2026 – 06:00 p.m. 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 CB_1 receptor, today announces its full year results for the year ended December 31, 2025.

Pier Vincenzo Piazza, CEO of Aelis Farma, stated: *"The year 2025 was marked by further progress in the clinical development of our two drug candidates, AEF0117 and AEF0217. For AEF0117, the final results of the Phase 2b study in cannabis use disorder (CUD) demonstrated that AEF0117 is capable of statistically significantly reducing cannabis use in patients with a strong motivation to quit and confirmed the excellent safety and tolerability of AEF0117. Regarding AEF0217, developed for the treatment of behavioral and cognitive impairments, the positive results in terms of safety, tolerability, and efficacy obtained in a Phase 1/2 study in people with Down syndrome enabled us to obtain regulatory authorizations and start the recruitment of an international multicenter Phase 2b study in France, Spain, and Italy. The first participant first visit took place in December 2025. This double-blind, placebo-controlled study will recruit 188 participants with Down syndrome, aged 16 to 32, who will be treated with either placebo or one of three doses of AEF0217. The study aims to confirm the positive effects of AEF0217 on adaptive behaviors and the favorable safety profile observed in the Phase 1/2 trial. Finally, our proprietary research platform has enabled us to select new CB_1-SSi with novel functional properties for a wider range of diseases involving the CB_1 receptor. For the year 2026, our main objective is to continue the Phase 2b clinical study with AEF0217 and initial preclinical proof-of-concept studies of our new compounds, all of which are already fully funded. 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 2025 (IFRS)

Simplified income statement[1] (in €K)	12/31/2025	12/31/2024
Revenue from ordinary activities	2,084	5,562
Research and development costs	(5,768)	(9,942)
General and administrative expenses	(2,513)	(3,355)
Operating income	**(6,198)**	**(7,735)**
Financial result	(229)	287
Income taxes	(8)	(8)
Net income (loss)	**(6,434)**	**(7,456)**

During the year ended December 31, 2025, the Company recorded income from ordinary activities of €2.1 million, corresponding to Research Tax Credit (€714,000), operating subsidies (€841,000) and studies rebilled without margin (€432,000) related to research programs conducted by Aelis Farma.

The decrease in revenue (-€3.5 million) is due to:

- -€2.7 million due to the finalization in 2024 of the recognition in revenue, in accordance with IFRS 15, of the residual portion of revenue related to the license option agreement with Indivior PLC for AEF0117 in cannabis use disorders. At the end of fiscal year 2024, all of the revenue associated with the lump sum payment received in 2021 had been recognized, representing a cumulative amount of €24.6 million.
- -€0.8 million due to the decrease in the Research Tax Credit (-€0.9 million) and studies rebilled without margin (-€0.7 million) offset by the increase in the share of operating subsidies reported in the income statement in 2025 (+€0.8 million).

Research and development costs

In K€	12/31/2025	12/31/2024
Raw materials, other purchases, and external expenses	(3,450)	(7,161)
Personnel costs	(2,113)	(2,371)
Intellectual property	(205)	(410)
Research and development costs	**(5,768)**	**(9,942)**

The change in research and development expenses (-42%) is mainly due to lower spending in 2025, particularly in view of the completion of the Phase 2b clinical trial of AEF0117. R&D expenses incurred in 2025 mainly cover:

- The completion of the Phase 2b clinical trial for AEF0117;
- The growth of preparatory activities for Phase 2b of AEF0217 (clinical and pharmaceutical development);
- The growth of activities on the proprietary research platform (initiation of early development and preclinical proof of concept).

[1] The annual financial statements were approved by the Board of Directors on March 30,2026. Audit procedures have been completed on these financial statements. The statutory auditors' certification report is currently being issued.

General and administrative expenses

In K€	12/31/2025	12/31/2024
Other purchases and external charges	(1,221)	(1,304)
Staff costs	(1,293)	(2,051)
General and administrative expenses	**(2,514)**	**(3,355)**

General and administrative expenses at December 31, 2025, amounted to €2,514,000, down €841,000 from the previous fiscal year. This decrease is mainly due to personnel expenses, more specifically the impact of workforce restructuring (-€0.8 million).

Operating income for the year ended December 31, 2025, therefore showed a loss of €6,198,000, compared with a loss of €7,735,000 for the year ended December 31, 2024. This change is mainly due to:

- Completion of clinical activities with AEF0117 and finalization of revenue recognition related to the license option agreement with Indivior PLC;
- Preparation of the Phase 2b study with AEF0217 in the treatment of cognitive deficits associated with Down syndrome, including regulatory non-clinical activities;
- Initiation of new proprietary platform activities related to the study of the molecular mechanisms of action and the in vitro specificity and toxicity of newly identified compounds.

Net financial income amounted to -€229,000 at December 31, 2025, compared with €287,000 at December 31, 2024. In 2025, it mainly consists of negative exchange rate differences (-€0.2 million), interest expenses on borrowings (-€0.3 million), and income from cash investments (+€0.2 million).

Net income was a loss of €6,434,000 in 2025, compared with a loss of €7,456,000 in the previous year.

Cash flow

Cash flow (in K€)	12/31/2025	12/31/2024
Cash flow from operating activities	**(5,353)**	**(11,831)**
Net cash flow from investing activities	**(841)**	**(190)**
Net cash flow from financing activities	**508**	**5,808**
Impact of exchange rate changes	(156)	53
Change in cash and cash equivalents	**(5,843)**	**(6,160)**
Opening cash position	14,051	20,211
Closing cash position	8,208	14,051

Financial structure

Structure financière (in K€)		12/31/2025	12/31/2024
Overall cash position (*)	**a**	**9,058**	**14,051**
Liquid assets	**b**	**8,208**	**14,051**
Gross financial debt	**c**	**(6,605)**	**(6,084)**
Net cash position	**b+c**	**1,603**	**7,967**
Overall net cash position	**a+c**	**2,453**	**7,967**

(*) The overall cash position as of December 31, 2025 includes €850,000 in term deposits classified as financial assets under IFRS 9, but which may be redeemed early at a reduced rate of return.

The year 2025 was marked in particular by the granting of two non-dilutive financing agreements totaling €2 million, generating net cash flow of €0.5 million (compared with €5.8 million in 2024).

At year-end 2025, Aelis Farma's financial structure remains solid, with a cash position of €9,058,000. The Company's cash burn is in line with its forecasts and the progress of its research and development program.

According to its forecasts and taking into account several measures already implemented, Aelis Farma believes that its current cash position will enable to finance its development until at least beginning of 2028.

Highlights of the full year 2025

New non-dilutive financing

In March 2025, the Company was granted a €1.5 million bank loan by Caisse d'Epargne, and in June 2025, a €1 million public loan by the Nouvelle-Aquitaine Region as part of its program to support innovative projects, the first tranche of €500,000 of which was paid in 2025.

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 analysis was published on March 26, 2025. These analyses show that:

- AEF0117 is well tolerated and without the adverse effects of CB_1 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 but not statistically significant effect on the primary endpoint (+228% vs. placebo), decreased the number of days of cannabis use per week (-55% vs. placebo; P=0.038) and 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, “Signaling Specific Inhibitors of the CB_1 Receptor (CB_1-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

Obtaining regulatory approvals issued by the relevant national authorities and ethics committees enabled the start of a Phase 2b clinical trial with the first participant first visit occurring in December 2025. This randomized, double-blind, placebo-controlled, parallel-group clinical trial plans to include 188 participants with Down syndrome, aged 16 to 32, in nine specialized clinical centers in France, Italy, and Spain (four in France, three in Italy, and two in Spain). Eligible participants are randomized into four groups receiving one of three doses of AEF0217 (0.1 mg, 0.2 mg, or 0.6 mg) or a placebo, orally, once a day for 24 weeks. It will be followed by a treatment-free eight-week follow-up period.
The primary objective of this study is to confirm and extend the positive Phase 1/2 results obtained with AEF0217, which showed a very favorable safety and pharmacokinetic profile, as well as statistically significant improvements in adaptive behaviors and brain activity in young adults with Down syndrome.

Strategy, outlook and major 2026 events

Based 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.

EMA Pediatric Committee issues favorable opinion on the AEF0217 Pediatric Investigation Plan for Down syndrome

In January 2026, the Pediatric Committee (PDCO) of the European Medicines Agency (EMA) issued a favorable opinion on the Pediatric Investigation Plan (PIP) for AEF0217, for the treatment of adaptive behavior disorders and cognitive impairments associated with trisomy 21 (Down syndrome). This major regulatory milestone for a treatment intended for use in children reinforces the credibility of the program, secures the regulatory requirements for the end of development, and improves the visibility of the European path toward marketing authorization (MA) for AEF0217. Positive results from the Phase 2b study would pave the way for further pediatric development of AEF0217.

Developing 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 functionally distinct families of compounds targeting the CB_1 receptor that could address a broad spectrum of diseases associated with CB_1 dysregulation. Some of these molecules have undergone early toxicity and pharmacokinetic testing, enabling initiation of proof-of-concept studies in diseases involving the CB_1 receptor.

Transfer of the Company's registered office

As part of the refocusing of its activities and teams, the Company changes its registered office to bring all its staff together in the new laboratories located at IECB[2], 2 rue Robert Escarpit in Pessac, France. The change of registered office will take effect on March 31, 2026. The gathering of all the teams is scheduled for mid-April 2026.

Presentation of financial accounts in 2026

Starting with the fiscal year beginning January 1, 2026, the Company will no longer publish its restated financial statements in accordance with IFRS. As the Company has no subsidiaries, it is not subject to this regulatory requirement. Therefore, the Half-Year Financial Report, which will be published following the Board of Directors' meeting approving the accounts as of June 30, 2026, will present the half-year results solely in accordance with French standards.

***

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

[2] IECB: Institut Européen de Chimie et de Biologie

improve adaptive behavior in young adults with Down syndrome (Trisomy 21) and has started a Phase 2b in Europe aiming to confirm its efficacy and safety in people with Down syndrome. The clinical results obtained with these 2 compounds have confirmed the safety and therapeutic activity of CB_1-SSi in humans. The Company also develops 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 new 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.

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

ISIN: FR0014007ZB4
Ticker: AELIS
C Compartment of Euronext Paris

Contacts

AELIS FARMA
Pier Vincenzo Piazza
Chief Executive Officer
contact@aelisfarma.com

NewCap
Dusan Oresansky / Thomas Cozzolino
Investor Relations
aelis@newcap.eu
+33 1 44 71 94 92

NewCap
Arthur Rouillé
Media Relations
aelis@newcap.eu
+33 1 44 71 00 15

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 filed with the *Autorité des Marchés Financiers* on April 28, 2025, under number D.25-0314.

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.