

Aelis Farma reports 2026 half-year financial results and presents progress and development outlook

The first half of 2026 was marked by:

- A positive opinion from the EMA Pediatric Committee on the Pediatric Investigation Plan for AEF0217, securing the development plan for this compound in Down syndrome;
- The continuation of the international Phase 2b clinical trial (France, Italy, Spain) with AEF0217 in people with Down syndrome, with recruitment progressing on track and a positive recommendation from the independent safety committee reviewing safety during the study;
- Progress in the development of new CB₁-SSi compounds from the Company's proprietary platform, particularly in obesity and associated metabolic diseases, supported by a €458,000 France 2030 grant; and
- Rigorous cost management, resulting in a solid cash position of €6.6 million as of June 30, 2026, providing financial visibility through early 2028, which could be further extended through additional non-dilutive funding.

Bordeaux, September 15, 2026 – 6h00 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 of the endocannabinoid system, today announces its financial results for the first half of 2026 and provides an update on its progress and development outlook.

Pier Vincenzo Piazza, CEO of Aelis Farma, stated: *“The first half of 2026 was notably focused on executing our clinical priority: the international Phase 2b study with AEF0217, which aims to improve adaptive behavior and cognitive abilities in people with Down syndrome. Following regulatory approvals and the first participant's first visit in December 2025, recruitment continued in all three study countries – France, Spain and Italy – in line with our expectations. The positive opinion received in January 2026 on the Pediatric Investigation Plan for AEF0217 also represents an important regulatory milestone for the continued development of this drug candidate in pediatric populations.*

For AEF0117, the final Phase 2b results confirmed the compound's pharmacological activity, its excellent safety profile and its potential in participants who are highly motivated to stop using cannabis. We are actively pursuing business development efforts to identify the most appropriate partner and development pathway to fully leverage these results.

At the same time, our proprietary research platform has enabled the advancement of new CB₁-SSi with functional properties distinct from AEF0117 and AEF0217, opening the potential to address new brain diseases linked to CB₁ dysregulation as well as peripheral diseases such as obesity and associated metabolic disorders. The award, in April 2026, of a €458,000 grant under the France 2030 program in Nouvelle-Aquitaine region is an important recognition of the scientific quality and potential of our new compound development program.

Thanks to rigorous and optimized management of our resources and the non-dilutive funding secured, our cash position stood at €6.6 million as of June 30, 2026, providing financial visibility through early 2028 while preserving our ability to execute our priority programs and create value.

Our roadmap remains clear: continue executing the AEF0217 Phase 2b study, advance the discovery and development of new CB₁-SSi compounds, and establish industry partnerships for AEF0117, AEF0217 and our platform.

We enter the second half of 2026 with confidence and the ambition to achieve further key milestones towards establishing Aelis Farma as a leading player in the development of innovative treatments for brain and peripheral diseases.”

Half-year results 2026 (French GAAP)

Simplified income statement ¹ (in €K)	06/30/2026	06/30/2025
Revenue from ordinary activities	449	343
Operating expenses	(3,157)	(4,755)
Operating income	(2,708)	(4,411)
Financial result	17	(259)
Income taxes	279	565
Net income (loss)	(2,412)	(4,105)

Since January 1, 2026, the Company has published its financial statements solely in accordance with French accounting standards. As the Company has no subsidiaries, it is not subject to the regulatory requirement to publish consolidated financial statements under IFRS.

In the first half of 2026, Aelis Farma recorded revenue from ordinary activities of €449,000, compared with €343,000 as of June 30, 2025, mainly corresponding to the portion of grants recognized over the period.

Operating expenses

In €K	06/30/2026	06/30/2025
Personnel costs	(1,048)	(1,322)
Other operating expenses	(2,109)	(3,433)
Operating expenses	(3,158)	(4,755)

Operating expenses amounted to €3.2 million in the first half of 2026, compared with €4.8 million in the first half of 2025. This 34% decrease mainly reflects the refocusing of activities on the AEF0217 Phase 2b clinical study, the completion of the main expenses related to previous clinical and non-clinical programs, and the continuation of the Company's cost-control plan.

R&D expenses incurred in the first half of 2026 mainly covered:

- the conduct of the international Phase 2b clinical study of AEF0217, initiated at the end of 2025 and currently recruiting in France, Spain and Italy;
- the continuation of activities on the proprietary research platform and the early development of new CB₁-SSi;
- preclinical proof-of-concept work, particularly within the “metabolism” program targeting obesity and associated metabolic diseases; and

¹ The interim financial statements were approved by the Board of Directors on September 15, 2026. Limited review procedures have been performed on these financial statements. The statutory auditors' limited review report is currently being issued.

- patent and intellectual property maintenance costs.

Operating income showed a loss of €2,708,000 as of June 30, 2026, compared with a loss of €4,411,000 as of June 30, 2025, an improvement of €1,703,000.

Financial income amounted to €17,000 as of June 30, 2026, compared with a loss of €259,000 as of June 30, 2025. It mainly comprised interest on outstanding loans (-€122,000), income from cash investments (€120,000) and a positive foreign exchange result (€20,000). As of June 30, 2025, it mainly reflected a foreign exchange loss and interest on outstanding loans.

For the first half of 2026, net income was a loss of €2,412,000, compared with a loss of €4,105,000 for the same period in 2025.

Cash flow

Cash flow (in €K)	06/30/2026	06/30/2025
Cash flow from operating activities	(1,970)	(3,988)
Net cash flow from investing activities	(2)	(6)
Net cash flow from financing activities	(483)	878
Impact of exchange rate changes	18	(155)
Change in cash and cash equivalents	(2,437)	(3,271)
Opening cash position	9,054	14,051
Closing cash position	6,616	10,791

Financial structure

Financial structure (in €K)		06/30/2026	12/31/2025
Liquid assets	a	6,616	9,054
Gross financial debt	b	(4,375)	(4,974)
Net cash position	a+b	2,241	4,080

Aelis Farma's financial structure remains solid, reflecting rigorous cost management and resulting in a cash position of €6.6 million as of June 30, 2026. Borrowings and financial debt amounted to €4.4 million, compared with €5.0 million as of December 31, 2025, resulting in a net cash position of €2.2 million.

During the period, the Company was awarded a €458,000 grant under the regional component of the France 2030 program in Nouvelle-Aquitaine, of which a first payment of €229,000 was received in June 2026.

Taking into account its cash position, the cost-control plan implemented and the non-dilutive funding secured, Aelis Farma believes it has the financial resources required to carry out its priority programs, with financial visibility through early 2028. At the same time, the Company continues to assess new financing and partnership opportunities that could further extend this visibility.

Highlights of the first half of 2026

Positive opinion from the EMA Pediatric Committee on the Pediatric Investigation Plan for AEF0217

On January 12, 2026, the Company announced that the Pediatric Committee ("PDCO") of the European Medicines Agency ("EMA") had issued a positive consensus opinion on the Pediatric Investigation Plan ("PIP") for AEF0217 in the treatment of adaptive behavior and cognitive impairments associated with Down syndrome.

The PIP provides for a progressive clinical development strategy for AEF0217 across the different pediatric age groups, subject to positive results from the ongoing Phase 2b study in participants aged

16 to 32 years. In particular, it specifies the studies to be conducted in children aged 6 to under 16 years, then 2 to under 6 years and, potentially, in children under 2 years of age.

The PDCO also accepted the current formulation of AEF0217 for pediatric use and considered the preclinical toxicology work already completed, as well as the proposed population pharmacokinetic modelling approach to determine and, where appropriate, adjust pediatric doses.

This positive opinion represents an important regulatory milestone for AEF0217. It confirms that the program is aligned with European pediatric development requirements, defines the studies to be conducted in the different age groups and reduces the risk of late regulatory requests that could delay a future marketing authorization application in Europe.

Continued recruitment in the AEF0217 Phase 2b clinical study

During the first quarter of 2026, the Company announced the successful start of recruitment in the international Phase 2b clinical study AEF0217-201 in people with Down syndrome. The first participant's first visit took place in December 2025, following receipt of the regulatory approvals required to conduct the study in France, Spain and Italy.

This multicenter, randomized, double-blind, placebo-controlled, parallel-group study is expected to enroll 188 participants with Down syndrome aged 16 to 32 years. Participants are randomized in a 1:1:1:1 ratio to receive once-daily treatment for 24 weeks with either placebo or one of three evaluated doses of AEF0217: 0.1 mg, 0.2 mg or 0.6 mg.

The primary objective of the study is to assess the effect of AEF0217 on adaptive behavior. The study will also evaluate its effects on cognitive function, sleep and quality of life, and confirm its safety and tolerability profile in a larger population and after a longer treatment duration than in the Phase 1/2 study.

Recruitment continued during the first half of 2026 at clinical centers open in France, Spain and Italy, in line with the Company's operational objectives. The Company expects to complete recruitment of the 188 participants before the end of 2026 and, subject to recruitment and participant follow-up progressing according to the planned timeline, to report study results before the end of 2027.

The study is being conducted as part of the European ICOD – Improving Cognition in Down syndrome project, which received €6 million in funding from the European Commission.

Development of new drug candidates on the Company's platform

Thanks to its diversified and proprietary CB₁-SSi library and screening platform, Aelis Farma has discovered several families of compounds with distinct functional properties targeting the CB₁ receptor, with potential to treat a broad spectrum of diseases associated with dysregulation of this receptor. Some of these molecules have 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 CB₁ hyperactivity plays an important role. They could also be developed for other brain and peripheral diseases involving CB₁ receptor dysregulation.

Award of a France 2030 grant

On April 7, 2026, the Company announced that it had been selected under the regional component of the France 2030 program in Nouvelle-Aquitaine and awarded a €458,000 grant under the "Projets d'Avenir Innovation" scheme. This non-dilutive public funding is intended to accelerate the Company's research and development activities in obesity and associated metabolic diseases.

The funding supports the identification, selection and characterization of new drug candidates from the Company's proprietary CB₁-SSi platform, as well as the initiation of preclinical development activities.

This grant recognizes the scientific quality and innovative nature of the Company's "metabolism" program. It strengthens Aelis Farma's ability to finance the early development stages of new

compounds while limiting recourse to dilutive financing. A first payment of €229,000 was received in June 2026.

Positive IDMC recommendation to continue the AEF0217 Phase 2b study

In July 2026, after the half-year closing date, the Independent Data Monitoring Committee (“IDMC”), following its review of the available safety data, recommended continuation of the AEF0217 Phase 2b study without any protocol changes. No safety concerns were identified during this review.

2026-2028 outlook

In the second half of 2026, the Company will focus its resources primarily on executing the programs with the greatest value-creation potential. This strategy is based first and foremost on continuing and completing recruitment in the international Phase 2b study AEF0217-201, which is evaluating the effects of AEF0217 on adaptive behavior and cognition in people with Down syndrome. The objective is to obtain the first results from this study in the fourth quarter of 2027. At the same time, the Company will continue to develop its proprietary library of new CB₁-SSi, with the aim of advancing several families of compounds with distinct functional profiles towards preclinical proof-of-concept in high-potential brain and peripheral indications, particularly obesity and associated metabolic diseases.

The Company will also continue active business development efforts across its portfolio. For AEF0117, the objective is to identify an industry partner able to finance and conduct the next development stages based on the clinical results obtained. For AEF0217, discussions will aim to prepare partnership, co-development or licensing options that could be activated in light of the Phase 2b results. Finally, the library of new CB₁-SSi is intended to open discussions with partners interested in earlier-stage programs and thereby create new opportunities to unlock value from the platform.

In 2027, the priority will be to complete treatment and follow-up of participants in the AEF0217-201 study and then analyze the clinical data, with results expected in the fourth quarter. At the same time, the Company will prepare the different scenarios for the continued development of AEF0217, including Phase 3 options, the required regulatory interactions and potential partnership structures. It will also seek to strengthen the value of AEF0117 and the library of new CB₁-SSi by developing more advanced partnership packages and expanding the available scientific and preclinical data.

This roadmap is accompanied by a gradual transformation of the Company’s operating model. Aelis Farma has begun to refocus its organization, reduce its cost base, optimize general and real-estate expenses and concentrate its R&D resources on AEF0217 and the new CB₁-SSi. The objective is to preserve key expertise, maximize the probability of success of the Phase 2b study and allocate available resources to the assets offering the greatest leverage for value creation.

By 2028, Aelis Farma aims to translate these scientific and clinical advances into strategic transactions for the Company. Subject to positive results from the AEF0217 Phase 2b study, the Company intends to leverage this asset to enter into an industry partnership, prepare the next stages of clinical development and strengthen its position in cognitive and behavioral impairments. It also aims to advance new CB₁-SSi drug candidates from its CB₁-SSi library in indications offering the greatest scientific, medical and economic potential.

Aelis Farma therefore intends to continue its transformation around three priorities: obtaining the results of the AEF0217 Phase 2b study, entering into new industry partnerships, and advancing future drug candidates from its platform. In parallel, the Company will continue to manage its resources rigorously in order to support these objectives and create long-term value.

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 consequently have strong potential for the treatment of many brain and peripheral organ diseases.

Aelis Farma currently has two first-in-class clinical-stage drug candidates. Clinical results obtained with both compounds have confirmed the safety and therapeutic activity of CB₁-SSi in humans. The first candidate, AEF0117, for the treatment of cannabis use disorder (CUD), has shown its ability to reduce cannabis use in two studies. The second candidate, AEF0217, for the treatment of cognitive impairments, showed a good safety profile and an improvement in adaptive behavior in young adults with Down syndrome in a Phase 1/2 study. On this basis, a Phase 2b study has started in Europe to confirm the efficacy and safety of AEF0217 in a larger cohort of participants with Down syndrome. The Company is also developing a portfolio of innovative CB₁-SSi for the treatment of other disorders associated with dysregulation of CB₁ receptor activity, including diseases involving peripheral organs, such as obesity and associated metabolic disorders. The new drug candidates developed by the Company belong to the same general pharmacological class, the CB₁-SSi, but have distinct functional effects enabling them to target different types of CB₁ receptor dysregulation and ensuring that the compounds are not substitutable for one another.

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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.