Press Release

Aelis Farma announces half-year financial results for 2024 and provides corporate and development update

- **A solid cash position of €12.6 million at June 30, 2024, not including the gross amount of €4.5 million share offering which occurred at the end of July and other non-dilutive financing currently being obtained, ensuring financial visibility assured until the end of 2026.**

The first half of 2024 was marked by:

- **The last patient last visit in the Phase 2B trial with AEF0117 for the treatment of cannabis use disorders (CUD) in April 2024. Although the primary endpoint was not met the preliminary results of this study show a statistically significant decrease in cannabis consumption in participants with moderate CUD.**
- **The end of recruitment for a phase 1/2 study with AEF0217 in people with Down syndrome. The results of the study will be announced in Q4 2024.**
- **The expansion of research capabilities with the transfer of the screening laboratory responsible for identifying new CB_1-SSi molecules to the IECB (*Institut Européen de Chimie et de Biologie*) in Pessac (Bordeaux).**

Bordeaux, France, September 25, 2024 – 6:00 pm CEST – Aelis Farma (ISIN: FR0014007ZB4 – Ticker: AELIS), a clinical-stage biopharmaceutical company specializing in the development of treatments for brain diseases, today announces its results for the first half of 2024 and provides an update on its development.

Pier Vincenzo Piazza, CEO of Aelis Farma, said: *"Overall, we are satisfied with the progress made over the first six months of 2024. Thanks to the efficiency, motivation, and commitment of our teams, key clinical milestones have been achieved with our two first-in-class drug candidates, AEF0117 and AEF0217.*

Regarding AEF0117, we have completed a Phase 2B clinical study in cannabis use disorders (CUD), the largest ever carried out in this field. The main goal of this study was to demonstrate that AEF0117 reduces cannabis use and to determine the optimal endpoints and doses to be used in future studies. The preliminary results of this study, released on September 4, 2024, showed that the primary endpoint (proportion of patients using cannabis $\leq$1 day per week) was not met. However, AEF0117 at the highest dose (1mg/day) led to a statistically significant reduction in quantitative measures of cannabis use in participants with moderate CUD, confirming that AEF0117 is pharmacologically active. We are currently completing further analysis in order to determine the next regulatory and development steps.

AEF0217, after proving to be safe, well tolerated and with good pharmacokinetic characteristics in healthy volunteers in Phase 1 studies, has just completed in June 2024 the recruitment of 30 participants in a Phase 1/2 study in people with Down syndrome. This multicenter study (Barcelona, Madrid) aims primarily to confirm the safety and pharmacokinetic properties of this drug candidate in people with Down's syndrome. The results of this study will be announced in Q4 2024.

Finally, at the end of July, we also announced the success of a €4.5 million fund-raising round aimed at strengthening the development of new CB_1-SSi molecules produced by our platform. This fund raising plus new non-dilutive funding currently being obtained, will ensure financial visibility until the end of 2026.

The results obtained with AEF0117 in Phase 2B confirm the pharmacological activity of the new pharmacological class developed by Aelis Farma, the "Signaling Specific inhibitors of the CB_1 receptor (CB_1-SSi)". We strongly believe that the CB_1-SSi represent a major discovery which could lead to the development of a whole new class of treatments for many pathologies with no therapeutic solution available today."

Half-year results 2024 (IFRS)

Simplified income statement[1] (in €K)	06/30/2024	06/30/2023
Revenue from ordinary activities	4,124	5,701
Research and development costs	(6,115)	(7,151)
General and administrative expenses and other operating income and expenses	(1,673)	(992)
Operating income	**(3,665)**	**(2,442)**
Financial result	83	813
Income taxes	0	(4)
Net income (loss)	**(3,583)**	**(1,633)**

In the first half of 2024, Aelis Farma recorded revenue from ordinary activities of €4.1 million, including:

- €2.2 million (vs. €3.7 million at June 30, 2023) 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 and yet to be recognized over the residual term of the option amounts to €0.4 million.
- €1.9 million (€2 million at June 30, 2023) in other income from ordinary activities, comprising the Research Tax Credit (€809,000), operating subsidies and studies charged back (€1,082,000) relating to Aelis Farma's research programs.

Research and development costs

In €K	06/30/2024	06/30/2023
Raw materials, other purchases and external expenses	(4,857)	(6,167)
Personnel costs	(1,041)	(907)
Intellectual property	(217)	(78)
Research and development costs	**(6,115)**	**(7,151)**

Research and development costs are decreasing compared to June 30, 2023, taking into account in particular the end of recruitment for the AEF0117 Phase 2B study at the end of the 2023 financial year; the first half of 2024 having been devoted essentially to monitoring the study data before the database is locked.

[1] The interim financial statements were approved by the Board of Directors on September 25, 2024. 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	06/30/2024	06/30/2023
Other purchases and external charges	(639)	(484)
Staff costs	(1,034)	(508)
General and administrative expenses	**(1,673)**	**(992)**

General and administrative expenses at June 30, 2024 amounted to €1,673,000, an increase of €681,000 compared to June 30, 2023. This increase mainly concerns personnel expenses, due to an increase in the number of employees and the valuation of BSA and BSPCE plans in accordance with IFRS 2.

The operating result recorded at June 30, 2024 was therefore a loss of €3,665,000, compared with a loss of €2,442,000 at June 30, 2023.

Financial income showed a profit of €83,000 at June 30, 2024, compared with a profit of €813,000 at June 30, 2023. This mostly comprises income from cash investments. At June 30, 2023, it corresponded mainly to financial income recognized on settlement of R&D transactions, which were self-hedged in dollars.

The net result was a loss of €3,583,000 for the first half of 2024, compared with a loss of €1,633,000 for the same period of 2023.

Cash flow

Cash flow (in €K)	06/30/2024	06/30/2023
Cash flow from operating activities	**(8,177)**	**(8,041)**
Net cash flow from investing activities	**(165)**	**(82)**
Net cash flow from financing activities	**719**	**(673)**
Impact of exchange rate changes	(4)	(149)
Change in cash and cash equivalents	**(7,626)**	**(8,945)**
Opening cash position	20,211	34,396
Closing cash position	12,585	25,450

Financial structure

Financial structure (in €K)		06/30/2024	12/31/2023
Liquid assets	**a**	**12,585**	**20,230**
Gross financial debt	**b**	**(5,085)**	**(4,040)**
Net cash position	**a+b**	**7,500**	**16,190**

Aelis Farma's financial structure remains strong, with a closing cash position of 12,6 M€ at the end of the first half of 2024. The Company's cash consumption is in line with its forecasts and the progress of its research and development program.

Given its cash position at June 30, 2024, the funds raised in the end-July 2024 transaction, and several non-dilutive financing in the process of being obtained, Aelis Farma expects to have sufficient cash to carry out its R&D program up to and including the fourth quarter of 2026.

Highlights of the first half of 2024

Last patient last visit for AEF0117 Phase 2B study in cannabis addiction

This pioneering study is the largest and best-controlled ever conducted in the field of cannabis addiction. The study enrolled 333 patients at 11 clinical centers in the US and the last patient last visit had been achieved in April 2024.

Completion of phase 1/2 enrolment with AEF0217 in the treatment of cognitive impairments in Down syndrome

In June 2024, the recruitment of 30 participants with Down syndrome for a multicenter phase 1/2 study (Barcelona, Madrid) was completed. The main objective of this phase 1/2 study is to evaluate the safety and pharmacokinetics of AEF0217 in people with Down syndrome. The results of this study will be announced in Q4 2024.

Transfer of the screening laboratory for the identification of new CB_1-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 m² 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 identify their mechanism of action for the treatment of various diseases.

Significant events after the closing

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 CB_1-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 CB_1 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 CB_1-SSi but have distinct functional effects which enable them to target different pathologies.

Publication of Phase 2B results with AEF0117 in participants with cannabis use disorders (CUD)

As indicated in the press release of September 4, 2024, the preliminary results of the Phase 2B with AEF0117 in CUD showed that:

- AEF0117 was well tolerated, and no safety concerns were identified.
- The primary endpoint, which measured the percentage of participants who reduced the number of days of use ≤1 day per week was not met by AEF0117.
- The endpoints measuring the quantitative consumption of cannabis showed at the highest dose of AEF0117 (1mg/day) consistent trends to decrease in the overall population and a statistically significant reduction in participants with moderate CUD, according to the DSM-5 diagnostic criteria.
- As already observed in the Phase 2A, these data confirm that AEF0117 is pharmacologically active, thus providing further validation of the new of drugs developed by Aelis Farma, the "Signaling Specific inhibitors of the CB_1 receptor (CB_1-SSi)".

The Company is currently investigating the results further to determine the best strategic and regulatory action plan.

Strategy & outlook

Thanks to its solid financial position, Aelis Farma intends to pursue the development of its various assets and to reach the next value-creation milestones.

Finalization of quality control and data analysis of Phase 2B results for AEF0117 in the treatment of cannabis addiction

The preliminary results and initial findings of this Phase 2B study should be considered as non-definitive. Quality control and complementary analysis of the data are currently underway before determining the next regulatory and development steps which will be communicated once this process is complete.

Indivior, Aelis Farma's partner for AEF0117, indicated that it did not currently expect to exercise the option on AEF0117 before seeing additional favorable clinical data.

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

Results from the Phase 1/2 study in people with Down syndrome are expected in Q4 2024.

Satisfactory safety and pharmacokinetic results would pave the way for a multicenter Phase 2 study, which could start in the first half of 2025. This study will aim to demonstrate the therapeutic effects of AEF0217 for the treatment of the cognitive deficits associated with Down syndrome.

Aelis Farma is also conducting additional preclinical studies to better determine the range of potential indications of AEF0217 in the broad field of cognitive deficits.

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 distinct families of CB_1 compounds that could address a broad spectrum of diseases associated with the CB_1 receptor.

Aelis Farma is initiating preclinical proof-of-concept studies and early toxicity and pharmacokinetic studies to select the drug candidates that could enter non-clinical development allowing first in human studies.

***

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 diseases.

Aelis Farma is currently developing two first-in-class clinical-stage drug candidates: AEF0117 for the treatment of cannabis related disorders, that has just completed a Phase 2B study in the United States in CUD, and AEF0217 for cognitive disorders, including those of Down syndrome (Trisomy 21), that has just completed recruitment in a Phase 1/2 study in Spain in people with Down syndrome, with results expected in Q4 2024. 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. 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.

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.

ISIN: FR0014007ZB4
Ticker: AELIS
B Compartment of Euronext Paris

Contacts

AELIS FARMA
Arsène Guekam
Chief Corporate Development Officer
contact@aelisfarma.com

NewCap
Dusan Oresansky / Aurélie Manavarere
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 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 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