Press release

Aelis Farma publishes half-year financial results for 2023 and confirms its development objectives

- **Acceleration of recruitment in AEF0117 phase 2b trial for the treatment of cannabis addiction and approval obtained in July 2023 by an independent Data Safety Monitoring Board (DSMB) to continue the trial with no amendments to the protocol**
- **Publication in *Nature Medicine* of an article presenting a series of studies describing the new pharmacological class developed by the company, cannabinoid receptor 1 signaling-specific inhibitors (CB_1-SSi), and its first drug candidate, AEF0117, for the treatment of cannabis use disorder (CUD)**
- **Continued clinical development of AEF0217 in Phase 1/2 in Down syndrome, and potential further expansion in autism spectrum disorders**
- **Two new families of CB_1 compounds discovered with potential application in CB_1-dependent psychiatric and neurological disorders**
- **Strong cash position at €25.5 million on June 30, 2023, ensuring financial visibility until the end of 2025 and allowing to reach the development objectives announced at the IPO**

Bordeaux, September 25, 2023 – 6:00 pm CEST – Aelis Farma (ISIN: FR0014007ZB4 – Ticker: AELIS), a clinical-stage biopharmaceutical company specializing in the development of treatments for brain disorders, today announces its results for the first half of 2023 and released an update on its development.

Pier Vincenzo Piazza, CEO of Aelis Farma, said: *"We are very pleased with the progress made over the first six months of 2023. Thanks to the efficiency, motivation, and commitment of our team, key planned clinical milestones have been achieved, allowing us to meet the ambitious targets set for our two first-in-class drug candidates, AEF0117 and AEF0217.*
For the second half of 2023, fulfilling our roadmap for those key assets will remain our priority, but we will also evaluate additional indications such us Phelan-McDermid syndrome (PMS) for AEF0217 and expand our pipeline. Our screening platform has made significant progress enabling us to identify new molecules different from AEF0117 and AEF0217. This discovery might pave the way for the treatment of other brain disorders and for Aelis Farma to become a leading player in this field."

Half-year results 2023 (IFRS)

Simplified income statement[1] (in €K)	06/30/23	06/30/22
Revenue from ordinary activities	5,701	4,251
Research and development costs	(7,151)	(7,093)
General and administrative expenses and other operating income and expenses	(992)	(1,800)
Operating income	**(2,442)**	**(4,642)**
Financial result	813	(5,710)

[1] The interim financial statements were approved by the Board of Directors on September 25, 2023. Limited review procedures have been performed on these financial statements. The statutory auditors' limited review report is currently being issued.

Income taxes	(4)	-
Net income (loss)	**(1,633)**	**(10,352)**

In the first half of 2023, Aelis Farma recorded revenue from ordinary activities of €5.7 million, including:

- €3.7 million (vs. €2 million at June 30, 2022) 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 €8 million.
- €2 million (€2.3 million at June 30, 2022) in other income from ordinary activities, comprising the Research Tax Credit (€883,000) and operating subsidies (€1,084,000) relating to Aelis Farma's research programs.

Research and development costs

In €K	06/30/23	06/30/22
Raw materials, other purchases and external expenses	(6,167)	(5,989)
Personnel costs	(907)	(1,045)
Intellectual property	(78)	(58)
Research and development costs	**(7,151)**	**(7,093)**

Research and development costs are stable compared to June 30, 2022, taking into account R&D activities on the Company's two compounds AEF0117 and AEF0217, as well as the research programs of Aelis Farma's discovery platform.

General and administrative expenses

In €K	06/30/23	06/30/22
Other purchases and external charges	(484)	(1,127)
Staff costs	(508)	(673)
General and administrative expenses	**(992)**	**(1,800)**

General and administrative expenses at June 30, 2023 amounted to €992,000, down €808,000 compared to June 30, 2022. This decrease mainly relates to other purchases and external expenses, which included in 2022 costs relating to the Company's IPO not charged to the share premium (€700,000).

The operating result recorded at June 30, 2023 was therefore a loss of €2,442,000, compared with a loss of €4,642,000 at June 30, 2022. This change was mainly due to:

- The timing of revenue recognition related to the license option agreement with Indivior PLC, based on the advancement of AEF0117 phase 2b costs, during the first half of 2023. €1,990,000 had been recognized in the first half of 2022;
- The costs associated with the Company's IPO in the first half of 2022.

Financial income showed a profit of €813,000 at June 30, 2023, compared with a loss of €5,710,000 at June 30, 2022. This mainly comprises financial income recognized on settlement of R&D transactions, which were self-hedged in dollars. At June 30, 2022, the non-cash financial expense associated with the conversion of convertible bonds on the date of Aelis Farma's IPO was recognized.

The net result was a loss of €1,633,000 for the first half of 2023, compared with a loss of €10,352,000 for the same period of 2022.

Cash flow

Cash flow (in €K)	06/30/23	06/30/22
Cash flow from operating activities	**(8,041)**	**(8,377)**
Net cash flow from investing activities	**59**	**(122)**
Net cash flow from financing activities	**(814)**	**22,644**
Impact of exchange rate changes	(149)	933
Change in cash and cash equivalents	**(8,945)**	**15,078**
Opening cash position	34,396	24,710
Closing cash position	25,450	39,789

Financial structure

Financial structure (in €K)		06/30/23	12/31/22
Liquid assets	**a**	**25,450**	**34,396**
Gross financial debt	**b**	**(4,305)**	**(3,823)**
Net cash position	**a+b**	**21,145**	**30,572**

Aelis Farma's financial structure remains robust at the end of the first half of 2023, with a net cash position of €21,145,000. The Company's cash consumption 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, in line with the strategy presented during the IPO, until at least the end of 2025.

Highlights of the first half of 2023

Publication of results from the development phases of AEF0117 in *Nature Medicine*

In June 2023, the prestigious scientific journal *Nature Medicine* published an article describing the new pharmacological class discovered by Aelis Farma, the CB_1-SSi, and the discovery and development of the first of these compounds, AEF0117, including the positive data from a phase 2a clinical trial in volunteers with cannabis addiction.

This article, the first to describe an Aelis Farma's drug, provides external validation of the efficacy and good tolerability of AEF0117, as well as of the CB_1-SSi in general.

Efficacy of AEF0217 in a mouse model of a genetic form of autism spectrum disorder

Data from preclinical studies demonstrating the efficacy of AEF0217 in a genetic mouse model of Phelan-McDermid syndrome (PMS) was presented at the 2nd European Conference on Phelan-McDermid syndrome in June 2023.

PMS is caused by deletion of chromosome 22q13 including the SHANK3 gene or a variation in the sequence of this gene. It is one of the genetic mutations most frequently observed in autism and a rare disease for which there is currently no treatment available. These mutations lead to development delays in multiple areas, particularly language, intellectual deficiency and often autism spectrum disorders.

The data presented was obtained in the context of a collaboration between several laboratories coordinated by Dr. Catalina Betancur. The results showed the ability of AEF0217 to reverse, in a statistically significant way, behavioral, cognitive and motor deficits, as well as a neurological alteration (cortical hyperactivity) considered as a neurobiological marker of autism. These promising results prompt the Company to analyze the feasibility of a clinical development of AEF0217 in PMS and more generally in autism spectrum disorder.

Strategy & outlook

Bolstered by its sound financial situation, Aelis Farma intends to continue the development of its various assets in accordance with the strategy presented at the time of its IPO:

Develop AEF0117 to address the adverse effects of excessive cannabis use

The phase 2b clinical trial with AEF0117 is continuing with a good pace of recruitment.

The opinion of the AEF0117 Data Safety Monitoring Board (DSMB), conducted on the first 115 patients treated for at least 4 weeks, was announced early July 2023. The DSMB did not find any serious adverse effect, or any significant adverse effect linked to the treatment. Aelis Farma was therefore given a positive and unanimous recommendation for the continuation, without any amendments to the protocol, of the phase 2b clinical trial of the AEF0117 for the treatment of cannabis addiction.

The first results of the study are expected mid-2024 as initially announced. Positive efficacy results from phase 2b could pave the way for phase 3 studies, the last step before a market authorization application can be filed. If Indivior exercises the license option at the end of the phase 2b, it will pay Aelis Farma a $100 million license fee (potentially by the end of 2024) and up to an additional $340 million subject to certain conditions, including if development, regulatory and commercial milestones are achieved, as well as royalties on net sales of AEF0117 of between 12% and 20%. Following the exercise of the option, all development, registration, and commercialization costs of AEF0117 will be borne by Indivior.

Develop AEF0217 to treat various cognitive deficits, including Down syndrome

The main objective for 2023 is to successfully complete the phase 1/2 study in Down syndrome people. Initially intended to be monocentric (IMIM, Barcelona), the study has been transformed into a multicentric study by adding two additional centers in Spain to obtain more robust results.

The main aim of this study is to analyze the safety and the pharmacokinetics of AEF0217 in people with Down syndrome. Obtaining satisfactory safety and pharmacokinetic results would pave the way for a multicentric phase 2b study, which could begin in 2024. The phase 2b will be aimed at confirming the therapeutic effects of AEF0217 in the treatment of cognitive disorders associated with Down syndrome. The development program of AEF0217 as a treatment of the cognitive deficits associated with Down syndrome has received a €6 million grant from the European community (ICOD Project No. 899986).

The efficacy of AEF0217 in a genetic mouse model of Phelan-McDermid syndrome (PMS), a common genetic cause of autism, opens also the potential application of AEF0217 to another field of neurodevelopmental disorders – Autism Spectrum Disorders (ASDs). The Company is taking and will take the necessary steps, with the help of international experts and consultations with regulatory authorities, to validate clinical trials designs, development plan and orphan disease designation for AEF0217 in PMS. These activities could put the Company in the position to potentially start the first clinical trial in PMS in Q4 2024.

Develop new drug candidates on the Company's proprietary platform

Thanks to its diversified and exclusive library of CB_1-SSi and screening platform, Aelis Farma has discovered two new distinct families of CB1 compounds, that should allow to address a broad spectrum of CB_1-dependendent psychiatric and neurological diseases. These new families of CB_1 compounds could start preclinical proof-of-concept-studies in the course of 2024.

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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 brain defense mechanism made by the team led by Dr. Pier Vincenzo Piazza, the Company's CEO, when he was director of Neurocentre Magendie of the 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 treatments for several brain diseases.
Aelis Farma is currently developing two first-in-class clinical-stage drug candidates: AEF0117 for the treatment of CUD, currently being tested in a phase 2b study in the United States; and AEF0217 for cognitive disorders, including those of Down Syndrome (Trisomy 21), currently in a phase 1/2 study in Spain in people with Down syndrome. 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.
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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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.