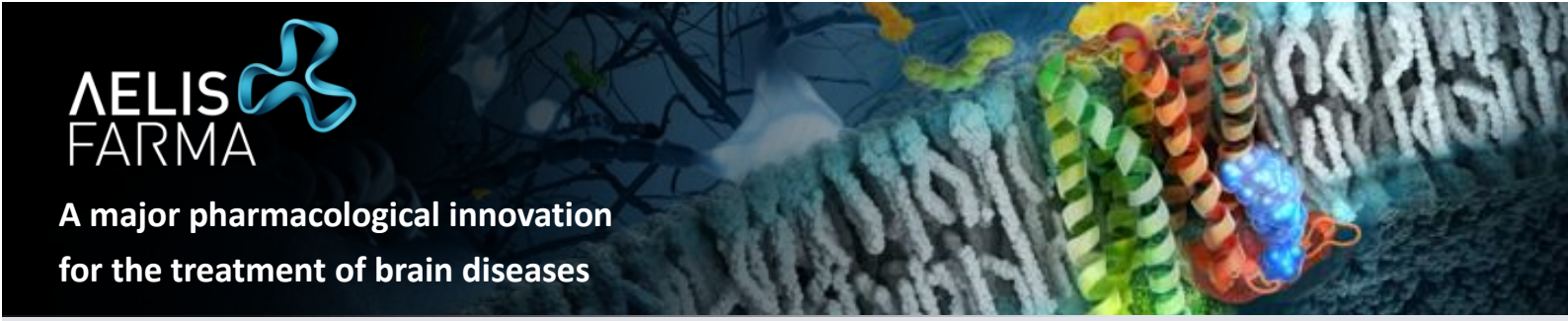

Press release

Aelis Farma reports its 2022 annual financial results and confirms its 2023 outlook

- **2022 objectives successfully met, notably in the development of the two drug candidates:**
  - **AEF0117: phase 2b study in the United States progressing as expected**
  - **AEF0217: the compound's safety and good tolerability in healthy volunteers have enabled the start of a phase 1/2 clinical trial in people with Down syndrome**
- **Strong cash position of €34.4 million at December 31, 2022, strengthened by the successful IPO on Euronext in February 2022, providing visibility through end 2025**

Bordeaux, April 3, 2023 – 5:45 p.m. CEST – Aelis Farma (ISIN: FR0014007ZB4 – Ticker: AELIS, PEA-PME eligible), a clinical-stage biopharmaceutical company specialized in the development of treatments for brain diseases, today announced its annual results for the year to December 31, 2022.

Pier Vincenzo Piazza, CEO of Aelis Farma, said: "*2022 was marked by a number of key events for Aelis Farma, beginning with our IPO, which enabled us to raise substantial financial resources in order to implement our development strategy. Thanks to the efficiency, motivation, and dedication of our team, key clinical milestones were achieved, enabling us to successfully meet our ambitious objectives, particularly the ones regarding our two first-in-class drug candidates. The phase 2b study in the United States for AEF0117, aimed at treating cannabis addiction, is progressing as planned and should provide the first results by mid-2024. AEF0217 has proven to be safe and well tolerated in healthy volunteers. These positive results represent real progress in the development of this treatment for neurodevelopmental cognitive disorders, including those associated with Trisomy 21 (Down syndrome). AEF0217 was thus able to enter at the end of 2022 a phase 1/2 study in people with Down syndrome which should be completed by the end of this year. Executing our 2023 roadmap is our priority and we are convinced that Aelis Farma is in an excellent position to become a leading player in the treatment of brain diseases*".

2022 annual results (IFRS)

Simplified income statement[1] (in €k)	2022	2021
Revenue from ordinary activities	8,364	10,762
Research & Development costs	(13,792)	(6,870)
General & Administrative expenses	(3,096)	(1,340)
Operating income	**(8,525)**	**2,552**
Financial result	(5,762)	(794)
Income taxes	(1)	(1,185)
Net income	**(14,288)**	**574**

In the year ended December 31, 2022, the Company recorded income from ordinary activities of €8.4 million, of which:

- €3.8 million 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 AEF0117 in disorders associated with cannabis use. The balance of the lump sum payment received and remaining to be recognized over the residual term of the option is €11.7 million. The decrease in this figure is due to the share of revenue recognized in 2021 in accordance with IFRS 15, i.e. €9,075 thousand, including €7,921 thousand associated with the signing of the contract.
- €4.6 million in other income from ordinary activities, consisting of Research Tax Credit (€2,121 thousand) and operating subsidies (€2,434 thousand) related to the research programs undertaken by Aelis Farma. Their increase compared to the previous year is correlated to the increase in Research & Development expenses incurred in 2022.

Research & Development costs

In €k	12/31/22	12/31/21
Raw materials, other purchases, and external expenses	(11,574)	(3,143)
Personnel costs	(2,052)	(1,808)
Intellectual Property	(166)	(1,919)
Research & Development costs	**(13,792)**	**(6,870)**

The increase in Research & Development costs (+101%) reflects the ramp-up of the development program for the drug candidates AEF0117 and AEF0217 and the full-year impact of the strengthening of the research teams, initiated in 2021. The decrease in intellectual property costs was partly due to the payment, in 2021, of royalties (€1,683 thousand) to patent owners following the signing of the sub-licensing option agreement with Indivior PLC.

General and administrative expenses at December 31, 2022, amounted to €3,096 thousand, including in particular costs related to the Company's IPO not charged to the share premium (€700 thousand), as well as additional costs related to the listing.

At December 31, 2022, the annual operating loss was thus -€8,525 thousand, compared to an operating profit of €2,552 thousand at December 31, 2021. This change was primarily due to:

- the progress made by the phase 2b study of AEF0117, in terms of opening clinical centers and recruiting patients;

[1] The annual financial statements were approved by the Board of Directors on March 31, 2023. The audit of these financial statements is complete. The certified auditors' report is in the process of being issued.

- the completion of phase 1 studies and launch of the phase 1/2 study of AEF0217;
- preclinical and pharmaceutical production activities (CMC) for both AEF0117 and AEF0217; and
- the schedule of revenue recognition associated with the licensing option agreement with Indivior PLC, based on the costs incurred by the phase 2b study of AEF0117.

Financial income showed a loss of -€5,762 thousand at December 31, 2022, compared to a loss of -€794 thousand at December 31, 2021. This change mainly reflects the impact of the conversion of convertible bonds on the date of Aelis Farma's Initial Public Offering. This non-cash financial expense corresponds to the difference between the fair value of the securities issued, based on the stock market price on the date of listing, and the nominal value of the initial debt.

The firm thus generated a net loss of -€14,288 thousand in 2022, compared to a profit of €574 thousand in 2021.

Cash flow

In €k	12/31/22	12/31/21
Cash flow from operating activities	**(13,051)**	**18,970**
Net cash flow from investing activities	**(86)**	**(212)**
Net cash flow from financing activities	**22,097**	**180**
Impact of exchange rate changes	723	1,235
Change in cash and cash equivalents	**9,684**	**20,172**
Opening cash position	24,710	4,538
Closing cash position	34,396	24,710

Financial structure

In €k		12/31/22	12/31/21
Liquid assets	**a**	**34,396**	**24,710**
Gross financial debt	**b**	**(3,823)**	**(7,917)**
Net cash position	**a-b**	**30,572**	**16,793**

Aelis Farma's financial structure was strengthened in 2022 by:

- the increase in the net cash position of €22.5 million from the capital increase carried out at the time of the Company's IPO on compartment B of Euronext Paris;
- the conversion into capital of the convertible bonds held by Inserm Transfert Initiative and the Nouvelle Aquitaine Region, leading to a €4,094 thousand reduction in the Company's gross debt from €7,917 thousand to €3,823 thousand.

The increase in cash in dollars related to the licensing option agreement with Indivior PLC enabled the recognition of a forex gain of €0.7 million.

The cash position of €34,396 thousand at December 31, 2022, thus represents a €9,684 thousand improvement compared to the previous year.

Taking in to account new non-dilutive finances, that the Company is confident to obtain, Aelis Farma has modified its forecast and now believes that its current cash level will enable to finance its development in accordance with the strategy presented at the time of the IPO until at least the end of 2025.

2022 annual highlights

Inclusion of the first patient in the phase 2b study with AEF0117 for treating cannabis addiction

At the beginning of June, Aelis Farma announced the enrollment of the first patient in the phase 2b study with AEF0117, its most advanced "CB_1-SSi" drug candidate, for the treatment of cannabis addiction. This study, coordinated by Prof. Frances Levin of Columbia University, is set to include some 330 patients in 11 clinical centers in the United States. The AEF0117 program has obtained overall funding of $7.8 million from the North American National Institute on Drug Abuse of the National Institute of Health (NIDA-NIH), including $4.5 million allocated at the end of 2021 for this new phase of development.

Positive results of the phase 1 studies undertaken on healthy volunteers with AEF0217 developed for treating cognitive deficits

In mid-November, Aelis Farma announced positive results from its safety trials in healthy volunteers and the authorization to initiate the first study in people with Down syndrome with its AEF0217 drug candidate for treating cognitive disorders. The single dose and multiple ascending dose trial of AEF0217 demonstrated the safety, tolerability, and good bioavailability of AEF0217 in healthy volunteers.

Inclusion of the first Down syndrome patient in the phase 1/2 study with AEF0217

On the basis of the positive results obtained in the phase 1 studies, the AEMPS (Spanish Agency of Medicines and Medical Products) authorized a phase 1/2 study with AEF0217 in adults with Down syndrome. On December 16, Aelis Farma announced the enrollment of the first patient in this study. The primary objective is to evaluate the safety and pharmacokinetics of AEF0217 in people with Down syndrome, and this study could also provide the first indications as to AEF0217's potential as a treatment for the cognitive deficits associated with Down syndrome.

The first patient was recruited by Prof. Rafael de la Torre Fornell's teams at the Hospital del Mar Medical Research Institute (IMIM) in Barcelona, Spain. Depending on the rate of enrollment, the study could be completed by the end of 2023.

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 level of enrollment. The results of the AEF0117 safety evaluation committee (DSMB), conducted on the first 110 patients treated for at least 4 weeks, are expected mid-2023. If they are positive, this will allow the study to continue through to expected completion in the first quarter of 2024. Positive efficacy results from phase 2b will pave the way for phase 3 studies, the last step before a marketing authorization application can be filed.

Develop AEF0217 to treat various cognitive deficits, including those of Down syndrome

In 2023, the main objective will be to successfully complete the phase 1/2 study. Obtaining satisfactory safety and pharmacokinetic results for AEF0217 in Down syndrome individuals would pave the way for a multicentric phase 2b study, which could begin in 2024, aimed at confirming the therapeutic effects of AEF0217 for the treatment of cognitive disorders associated with Down syndrome. The program to develop AEF0217 as a treatment for cognitive deficits associated with Down syndrome has received a €6 million grant from the European community (ICOD Project No. 899986).

Aelis Farma is also working to expand the study of AEF0217's efficacy with regard to other indications, such as cognitive disorders associated with other neurodevelopmental diseases, or aging.

Identify new drug candidates

Given the involvement of the CB_1 receptor in numerous pathologies and thanks to its diversified and exclusive library of CB_1-SSi, Aelis Farma is continuing to characterize new CB_1-SSi liable to address other brain disorders dependent on the CB_1 receptor.

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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 new natural brain defense mechanism by the team led by Dr. Pier Vincenzo Piazza, the Company's CEO, when he was Director of the INSERM Magendie Neurocenter in Bordeaux. By reproducing this natural mechanism, CB_1-SSi appear to be capable of selectively inhibiting the disease-related activity of the CB_1 receptor without disrupting its normal physiological activity. They thus have significant potential for the treatment of numerous brain diseases.

Aelis Farma is developing two first-in-class clinical-stage drug candidates: AEF0117 for the treatment of disorders due to excessive cannabis use, currently 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. The Company also has a portfolio of 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**.

ISIN: FR0014007ZB4
Ticker: AELIS
B Compartment of Euronext Paris

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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 registration document approved by the Autorité des Marchés Financiers on January 14, 2022, under number I.22-003.

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.