

## **Aelis Farma reports 2021 annual financial results and confirms its 2022 outlook**

- **An exceptional fiscal year 2021, marked by positive phase 2a results for AEF0117, the recognition of the first sub-licensing revenues thanks to the signature of an industrial partnership with Indivior PLC, and securing major grants for AEF0217 (EU's Horizon 2020 program) and AEF0117 (NIH-NIDA USA).**
- **A solid financial structure, with a closing cash position of €24.7 million, strengthened by the success of the IPO carried out at the beginning of 2022, which raised €25.3 million.**

**Bordeaux, April 4, 2022 - 7:00 a.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 ended December 31, 2021.

**Pier Vincenzo Piazza, CEO of Aelis Farma,** said: *"On behalf of Aelis Farma, I would like to thank once again all our shareholders, both long-standing and new, as well as our partner Indivior, for their contribution to the success of our initial public offering in February. The fundraising of more than €25 million realized on this occasion gives us the necessary means to accelerate the development of Aelis Farma and deploy its strategic plan presented to the financial community. The success of this transaction is based on the solid foundations put in place in particular during the 2021 financial year with the signature of our first industrial partnership with Indivior PLC, through an option-license agreement for AEF0117 to treat the adverse effects of excessive cannabis use. This asset, which is the most advanced of our pipeline and is on the verge of a phase 2b clinical study, also received a new grant of \$4.5 million from the U.S. National Institute of Health (NIH) at the end of 2021. Our second drug candidate, AEF0217, has received a European grant of €6 million for the ICOD program which support the clinical program aiming to confirm its potential to treat cognitive deficits of Down syndrome (Trisomy 21). These different programs make Aelis Farma a company on the forefront of the brain diseases space, a position that, with the support of our investors, we are convinced to be able to consolidate and eventually become one of the leading players in this sector that has significant unmet medical needs."*

## Annual results 2021 (IFRS)

Simplified income statement <sup>1</sup> (in €k)	2021	2020
Revenue from ordinary activities	10,762	1,137
Research and development costs	(6,870)	(3,388)
General and administrative expenses and other operating expenses and income	(1,340)	(589)
<b>Operating income</b>	<b>2,552</b>	<b>(2,840)</b>
Financial result	(794)	(202)
Income taxes	(1,185)	956
<b>Net income (loss)</b>	<b>574</b>	<b>(2,086)</b>

In June 2021, the Company entered into a sub-license option agreement with Indivior PLC, the leading addiction treatment group, for AEF0117 to treat cannabis related disorders, addictions, and other compulsive behaviors. Aelis Farma's revenues from this contract are as follows:

- upon signing the contract, the Company received an upfront payment of \$30 million;
- if the option is exercised by Indivior PLC, the Company will receive a lump sum payment of \$100 million;
- depending on the achievement of technical, regulatory and commercial milestones supplementary payments of up to \$340 million;
- royalties on net sales between 12% and 20%.

The accounting principles applied to the revenues from this contract, resulting from IFRS 15, have led to the recognition of revenues of €9,075,000 for the year 2021. The balance of the upfront payment received, i.e., €15,541,000, will be recognized over the remaining term of the option.

Other income from ordinary activities (€1,687,000) consists of the Research Tax Credit (€1,089,000) and operating grants (€598,000) related to the research programs led by the Company. Their increase compared to the previous year is correlated to the increase in research and development expenses incurred during the year.

## Research and development costs

In €k	31/12/21	31/12/20
Raw materials, other purchases and external expenses	(3,143)	(1,741)
Personnel costs	(1,808)	(1,351)
Intellectual Property	(1,919)	(296)
<b>Research and development costs</b>	<b>(6,870)</b>	<b>(3,388)</b>

The increase in research and development expenses (+103%) reflects the ramp-up of the development program for drug candidates AEF0117 and AEF0217, the strengthening of research teams, and the

<sup>1</sup> The annual accounts were approved by the Board of Directors on April 1<sup>st</sup>, 2022. The audit of these accounts has been completed. The certified auditors' report is in the process of being issued.

increase in intellectual property expenses related to the payment of royalties to patent owners following the signature of the sub-licensing option agreement with Indivior PLC (€1,683,000).

The operating result at December 31, 2021 was a profit of €2,552,000 compared to a loss of €2,840,000 at December 31, 2020. This change is mainly due to the recognition of revenues from the license option contract signed in 2021 with Indivior PLC.

The financial result shows a loss of -€794,000 at December 31, 2021 compared to a loss of -€202,000 at December 31, 2020 in particular due to the application of the IFRS standard on financial instruments applied to the convertible bonds contracted by the company in 2019.

The net result for the year 2021 is a profit of €574,000 compared to a loss of -€2,086,000 for the previous year.

## Cash flow

In €k	31/12/21	31/12/20
<b>Cash flow from operating activities</b>	<b>18,970</b>	<b>(2,478)</b>
<b>Net cash flow from investing activities</b>	<b>(212)</b>	<b>(34)</b>
<b>Net cash flow from financing activities</b>	<b>180</b>	<b>1,277</b>
Effect of exchange rate changes	1,235	-
<b>Change in cash and cash equivalents</b>	<b>20,172</b>	<b>(1,235)</b>
Opening cash position	4,538	5,771
Closing cash position	24,710	4,538

The fiscal year 2021 was characterized by the strengthening of the company's financial structure thanks to the revenues from operating activities resulting from the signing of the license option agreement with Indivior PLC, and the payment of \$30 million upon signing of the agreement. The positive evolution of this cash flow in dollars allowed the recognition of a foreign exchange gain of €1.2 million. The cash position at December 31, 2021 of €24,710,000 thus reflects an improvement of €20,172,000 in cash compared to the previous year.

## Financial structure

In €k		31/12/21	31/12/20
<b>Liquid assets</b>	<b>a</b>	<b>24,710</b>	<b>4,538</b>
<b>Gross financial debt</b>	<b>b</b>	<b>7,917</b>	<b>6,336</b>
<b>Total net financial debt</b>	<b>b-a</b>	<b>(16,793)</b>	<b>1,798</b>

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

- the net proceeds of €22.1 million from the capital increase carried out at the time of the Company's listing on compartment B of Euronext Paris;
- the conversion into capital of the convertible bonds held by Inserm Transfert Initiative and the Nouvelle-Aquitaine Region, resulting in a decrease of €3,591,000 in gross indebtedness, from €7,917,000 to €4,326,000.

The Company's current cash position allows it to finance the development of Aelis Farma in accordance with the strategy presented during the IPO.

## Strategy & outlook

In 2022, with a financial position strengthened by the funds raised during the IPO in February of €25.3 million, the Company intends to pursue the development of its various assets and accelerate the ramp-up of CB<sub>1</sub>-SSi development:

### 1. Development of AEF0117 to treat the adverse effects of excessive cannabis use

A phase 2b clinical trial, including approximately 330 patients and whose protocol has been discussed with the FDA, will start in the second quarter of 2022 in the United States, in accordance with expectations, to evaluate the efficacy of AEF0117 for the treatment of cannabis addiction. The study will be coordinated by its principal investigator, Prof. Frances Levin of Columbia University. The new development phases of AEF0117 have received a grant of \$4.5 million from NIH, which had already provided funding for phases 1 and phase 2a of \$3.3 million.

### 2. Development of AEF0217 to treat various cognitive deficits, including those of Down syndrome (Trisomy 21)

AEF0217 is currently being evaluated in phase 1 clinical studies in healthy volunteers, with no significant adverse events reported to date in the first five cohorts of subject. Results from these studies will be available in the second quarter of 2022.

A phase 1/2 clinical study of AEF0217 in Down syndrome subjects is planned to start in the fourth quarter of 2022. These studies could provide initial efficacy results in the first half of 2023. This clinical program is being conducted in the framework of the "Improving Cognition in Down syndrome" ("ICOD") consortium in collaboration with the Institut Hospital del Mar d'Investigacions Mèdiques ("IMIM") in Barcelona and other European clinical centers. The European Union's Horizon 2020 program has awarded the ICOD project a grant of €6 million (H2020 Program N° 899986).

Aelis Farma also plans to finalize in 2022 the preparation of the phase 2 research program for AEF0217, which will expand the study of the compound's efficacy to other indications, such as cognitive disorders associated with Fragile X syndrome or aging, in which AEF0217 has demonstrated efficacy in preclinical models.

### 3. Development of new drug candidates via the proprietary platform

Given the involvement of the CB<sub>1</sub> receptor in numerous pathologies and with its diversified and proprietary library of CB<sub>1</sub>-SSi, Aelis Farma plans to pursue the characterization of new CB<sub>1</sub>-SSi that may address other CB<sub>1</sub> receptor-dependent brain diseases.

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## About AELIS FARMA

Founded in 2013, Aelis Farma is a biopharmaceutical company that is developing a new class of drugs, the Signaling Specific inhibitors of the CB<sub>1</sub> receptor of the endocannabinoid system (CB<sub>1</sub>-SSi). These new molecules hold great potential in the treatment of many brain diseases. CB<sub>1</sub>-SSi were developed by Aelis Farma on the basis of the discovery of a new natural defense mechanism of the brain made by the team of Dr. Pier Vincenzo Piazza, CEO of the Company, when he was Director of the Inserm Magendie Neurocenter in Bordeaux. For these discoveries, Dr. Piazza was awarded the Inserm Grand Prix and the Grand Prix of Neurology of the French Academy of Sciences, which are among the most prestigious French prizes in medicine and neurology.

Aelis Farma is developing two first-in-class drug candidates that are at the clinical stage, AEF0117 and AEF0217, and has a portfolio of innovative CB<sub>1</sub>-SSi for the treatment of other diseases associated with dysregulation of CB<sub>1</sub> receptor activity.

AEF0117, which targets the disorders due to excessive cannabis use (addiction and psychosis), has demonstrated efficacy in a phase 2a clinical trial and will enter a phase 2b clinical trial in the United States in 2022. Aelis Farma has an exclusive license option agreement with Indivior PLC, a leading pharmaceutical group in the treatment of addiction, for the development and commercialization of AEF0117 to treat disorders linked to excessive cannabis use. As part of this agreement, Aelis Farma received \$30 million (option payment). If Indivior exercises the license option at the end of the phase 2b, Aelis Farma will receive a \$100 million license fee (potentially in 2024) and up to \$340 million in additional payments contingent upon the achievement of development, regulatory and commercial milestones, as well as royalties on net sales of AEF0117 ranging between 12% and 20%.

AEF0217, which targets various cognitive disorders including those associated with Down syndrome, is successfully progressing in its phase 1/2 program and could provide the first evidence of efficacy in the first half of 2023. This compound has undergone an extensive preclinical proof-of-concept program using highly innovative and highly predictive tests to assess cognitive functions. In this context, AEF0217 has demonstrated its ability to completely reverse cognitive deficits observed in several models of neurodevelopmental disorders, such as Down syndrome and Fragile X syndrome, as well as in models of certain cognitive deficits associated with aging.

Based in Bordeaux, within the Magendie Neurocenter, Aelis Farma has a team of 24 highly qualified employees and has benefited from investments from the Nouvelle-Aquitaine Region, Inserm Transfert Initiative, Bpifrance, regional funds ACI, NACO and Aquinvest and IRDI Capital Investissement.

For more information: [www.aelisfarma.com](http://www.aelisfarma.com)



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