PRESS RELEASE
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NFL BIOSCIENCES: 2024 FIRST-HALF BUSINESS AND EARNINGS UPDATE

Key stages completed with the development of NFL-101, the smoking cessation drug candidate, with preparations for Phase 3 underway

Advances with the co-development of NFL-301, a drug candidate to reduce alcohol consumption

Available cash horizon through to the third quarter of 2025, with €3 million raised through a capital increase in April

NFL BIOSCIENCES (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company developing botanical drugs for the treatment of addictions, is reporting its results for the first half of 2024, approved by the Board of Directors on September 26, 2024. On this occasion, NFL Biosciences looks back on the achievements from the past year, including the significant advances made with the clinical trials for NFL-101, a smoking cessation treatment, and the pre-development stages for NFL-301, a treatment for combating excessive alcohol consumption.

Key stages completed with the development of NFL-101, the smoking cessation drug candidate, with preparations for Phase 3 underway

NFL-101 is a nicotine-free tobacco extract derived from a subcutaneous desensitization treatment for tobacco allergies in tobacco factory workers. NFL-101 has already been tested in two clinical trials: a Phase 1 study - CESTO - confirmed its safety and a Phase 2a study - PRECESTO - confirmed its ability to significantly reduce smoking satisfaction in smokers who are not looking to quit. During the first half of 2024, NFL Biosciences successfully completed various key stages with the development of NFL 101:

Success of the study with the CEA on the mechanism of action of NFL-101

In January 2024[1], NFL Biosciences and the French Atomic Energy and Alternative Energy Commission (CEA) presented the results of their study researching the mechanism of action of NFL-101 on an animal model.

This study highlighted a disruptive mechanism of action demonstrating:

- the ability of NFL-101 to reduce craving by the restoration of normal brain activity in the region of the brain associated with this craving;
- a targeted and specific action which does not lead to any changes in brain activity in mice not exposed to tobacco.

The results indicate that there is communication between the immune system and the central nervous system, a different mode of action than with the current smoking cessation drugs, which directly target nicotinic receptors.

These observations represent a major advance for NFL-101. The action on craving is encouraging, with this mechanism recognized as the major challenge with tackling smoking through drugs.

Specifically, the results were presented in June at the Albatros congress, one of the most important annual events for the treatment of addictology in France. They were also published in the American Chemical Society's ACS Chemical Neuroscience, an international peer-reviewed monthly scientific journal, which is ranked as one of the top 7% most widely quoted scientific journals. The scientific paper entitled "*Brain glucose metabolism as a readout of the CNS impact of cigarette smoke exposure, withdrawal, and the effects of NFL-101, as an immune-based drug candidate for smoking cessation therapy*" is co-signed by scientists from the CEA, CNRS, Inserm, BioMaps, Paris-Saclay University (91401 Orsay), Paris Cité University, INSERM, PARCC, (75015, Paris), the immunology department, APHP, Hôpital Européen Georges Pompidou (HEGP), Hôpital Necker (Paris, France) and by NFL Biosciences.

1 See press release from January 30, 2024

CESTO II, Phase 2 study, shows a comparable efficacy to Champix®, without its side effects

Launched in December 2021, CESTO II is a multicentric, randomized, double blind and placebo controlled Phase 2 clinical trial, with three arms (dose 1, dose 2 and placebo), conducted with 318 smokers (106 per arm) looking to quit. The study was conducted in nine clinical centers in France with a 12-month follow-up period: the Clinical Investigation Centers (CIC) at CHU university hospital centers in Bordeaux, Clermont-Ferrand, Dijon, Lorient, Marseille, Montpellier, Poitiers and Rennes, as well as the Eurofins-Optimed research institute (Grenoble).

The results of the CESTO II study, published on July 15, 2024[2], confirmed the potential of NFL-101 as a smoking cessation treatment and paved the way for the transition to Phase 3. CESTO II highlighted an effect that compares favorably with current treatments, with NFL-101 surpassing the efficacy levels of nicotine substitutes and comparable to Champix®, a treatment with serious side-effects, which requires two daily doses for 12 weeks, compared with two administrations for NFL-101.

Moreover, NFL-101 confirmed its excellent safety profile: the two doses of NFL-101 were very well tolerated, with no serious adverse events, while less than 10% of cases recorded transient adverse effects, of mild to moderate intensity.

Lastly, by demonstrating a clinically relevant effect size, CESTO II also made it possible to select the optimal dose, which is the primary goal of a Phase 2 study, despite the fact that one clinical center, which has a tobacco addiction unit, contributed to a significant increase in the placebo effect. Doubling the dose (dose 2) did not provide any additional efficacy, which confirms that the anticipated dose 1 is justified.

The fundamental objectives of a Phase II study - highlighting an effect that compares favorably with current treatments, confirming the excellent safety profile, and confirming the dose - have been achieved, making it possible to prepare for the transition to the Phase 3 clinical trial, the final step before the marketing authorization (MA) application.

Further results will be released in October and the full results will be submitted for publication in an international peer-reviewed journal and presented at scientific conferences.

Preparation for the transition to Phase 3

The development of the Phase 3 batch manufacturing program, representative of future commercial batches, was launched at the start of 2024 and has been ramped up following the results of CESTO II.

NFL Biosciences aims to have effective control over the manufacturing process and industrialization of NFL-101, from the sourcing of raw materials to the mobilization of industrial partners (CDMO), to ensure that Phase 3 is carried out under optimum conditions, within a quicker timeframe. The optimization of NFL-101 manufacturing is also underway. The effective management of this complex industrial process and the resulting acceleration with the transition to Phase 3 represent considerable assets to capitalize on and create value through the NFL-101 project under the best conditions with one or more licensing agreements.

Advances with the co-development of NFL-301, a drug candidate to reduce alcohol consumption

NFL-301 is subject to a co-development agreement, set up at the start of 2022, with Athena Pharmaceutiques, a leading French player for the development and production of oral delivery drugs, to develop a prolonged-release form of kudzu plant extracts in microgranule form. NFL Biosciences aims to develop the first oral delivery drug based on kudzu extracts to tackle excessive alcohol consumption. NFL-301 is covered by an initial patent application, filed in the United States in July 2023.

In the middle of December 2023, NFL Biosciences submitted a pre-IND application to the FDA in the United States. The aim is to formalize the NFL-301 development program, covering the manufacturing and quality control methods, as well as the preclinical data and clinical trials.

The FDA issued its response to this in May 2024. Following the meeting of 17 FDA experts and the FDA report, NFL Biosciences will gradually roll out the NFL-301 development plan, in line with the FDA's expectations. To benefit from the botanical drug candidate status, the kudzu extract used to develop NFL-301 will need to comply with the botanical drug candidate development guidance[3]. The formulation retained will need to be presented to the FDA prior to the clinical trial authorization application. This status makes it possible to considerably streamline the preclinical program, particularly before phase 1.

(2) See press release from July 15, 2024

(3) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/botanical-drug- development-guidance-industry

With this second indication, targeting the major public health issue of excessive alcohol consumption, NFL Biosciences is once again setting out its commitment to delivering new, natural, safer and more effective therapeutic solutions for the treatment of addictions.

Available cash horizon through to the third quarter of 2025, with €3 million raised through a capital increase in April

In April 2024, NFL Biosciences successfully completed a round of fundraising for €3,089,175.75 through capital increases with shareholders' preferential subscription rights waived, placed with professional investors for €2.5 million and with retail investors through the PrimaryBid platform for €0.6 million. This enabled NFL Biosciences to push back its cash horizon to the third quarter of 2025. NFL Biosciences is also continuing to apply for non-dilutive financing solutions with French and European institutions.

65% of the funds are allocated to anticipating the Phase 3 requirements for NFL-101 to set up a licensing agreement under optimal conditions, with 20% covering the formalization of the NFL-301 development plan, and 15% assigned to NFL Biosciences' day-to-day operations.

The Transaction was put in place and carried out under the 10th, 12th and 13th resolutions from the Company's Extraordinary General Shareholders' Meeting on June 27, 2023 (the "General Meeting") at a price of €2.05 per share, representing a discount of 21.67% compared with the volume-weighted average price of NFL Biosciences shares over the last five trading sessions (i.e. from April 4 to 10, 2024) equal to €2.6171 and 20.23% compared with the closing price of NFL Biosciences shares on Thursday April 11, 2024 of €2.57.

The settlement and delivery of the new shares and their listing on the Euronext Growth Paris multilateral trading facility under the same ISIN code (FR0014003XT0) took place on April 16, 2024. In connection with this operation, NFL Biosciences also made a commitment to not carry out any capital increase based on new shares for a period of six months from the completion of the Transaction without prior approval from Invest Securities.

Following the Transaction, NFL Biosciences' share capital was increased to €288,410.52, split into 9,613,684 ordinary shares with a par value of €0.03, all of the same category.

Partnership strategy

NFL Biosciences is continuing to identify pharmaceutical partners that are interested in the addiction field for the next steps with the development of NFL-101.

Following the positive results announced during the year, NFL Biosciences resumed discussions that were already underway and identified potential new partners.

Concerning the partnership in India with THEMIS PHARMACEUTICALS, NFL Biosciences has concluded that the activities in India were not progressing as quickly as expected. In this context, NFL Biosciences will terminate this partnership and look to include India within a broader partnership.

2024 first-half earnings and financial position

The financial statements for the first half of 2024 (six-month period from January 1, 2024 to June 30, 2024), prepared in accordance with French GAAP, were approved by the Board of Directors during its meeting on September 26, 2024. The accounts have been subject to a limited review by the statutory auditors. The HY 2024 financial report is made available today and can be accessed at www.nflbiosciences.com, "Investors" menu, "Documents" section.

Corporate accounts (€)	**Jun 30, 2024[2]** ***(6 months)***	**Jun 30, 2023[2]** *(6 months)*	**Dec 31, 2023[1]** ***(12 months)***
Net revenues		-	-
Total operating income	40	94,777	200,011
EBIT	(896,065)	(2,382,387)	(4,230,422)
Financial income	42,779	71,388	118,554
Non-recurring income	-	-	-
Corporate income tax	(121,777)	(200,349)	(366,393)
Net income	**(731,509)**	**(2,110,650)**	**(3,745,476)**

Shareholders' equity	**2,288,261**	**1,907,772**	**349,945**
Conditional advances	1,190,000	1,208,977	1,190,977
Intangible assets (patents)	163,813	122,785	141,041
Liabilities	1,530,916	2,461,532	2,429,706
- Of which financial liabilities	53,356	72,727	62,174
- Of which operating liabilities	1,477,560	2,283,580	2,367,532
- Of which prepaid income		105,225	
Cash and cash equivalents	3,546,153	3,359,459	2,338,044
Balance sheet total	**5,009,176**	**5,578,281**	**3,970,628**

(1) Accounts audited and certified.
(2) Accounts subject to a limited review by the statutory auditors.

As NFL Biosciences is still in the clinical trials development stage, it did not record any revenues during the last three years. The Company recorded a non-material amount of operating income at June 30, 2024, compared with €94K at June 30, 2023, which corresponded to an operating grant received from Bpifrance for the PRECESTO program during the first half of 2023 (out of a total of €200K recorded over the full year in 2023).

EBIT totaled €(0.9) million at June 30, 2024, compared with €(2.4) million at June 30, 2023, with operating expenditure concerning the programs launched by the Company during the first half of the year, i.e. the study on the mechanism of action with the CEA and the finalization of the CESTO II study.

The €43K of financial income is linked primarily to the investment of cash surpluses during the first half of the 2024.

The research tax credit (CIR), assessed based on half-year expenses, came to €193K at June 30, 2024. The research tax credit applied for in 2023 for €373K was reimbursed for €298K. The €75K balance is subject to discussions concerning the period to be retained. As a precautionary measure, this amount has been canceled and is therefore deducted from the amount for the first half of the year.

As a result of these operations, net income for the period came to €(0.7) million, compared with €(2.1) million for the first half of 2023.

At June 30, 2024, the Company had €2.3 million of shareholders' equity and €3.5 million of available cash, linked primarily to the capital increase carried out in April 2024 for €3 million. NFL Biosciences has €53K of financial liabilities, corresponding to the government-backed loan taken out in December 2020 in connection with the support measures put in place during the health crisis. The first installment was repaid in December 2022, with the final installment to be paid in November 2026. Repayable advances represented €1.2 million at June 30, 2024, corresponding to the two Bpifrance grants awarded in previous years. The Company is still due to receive €450K of the repayable advance relating to CESTO II. Repayments will start during the fourth quarter of 2025.

Outlook for 2024

NFL Biosciences has successfully completed various major stages with the development of its drug candidate NFL-101 for smoking cessation and laid the foundations for the development of its second drug candidate NFL-301 for reducing excessive alcohol consumption. During the second half of the year, discussions with potential partners are continuing to progress and the preparatory steps are underway to better capitalize on the Phase 3 study for NFL-101.

For 2024, the Company is continuing to move forward with three complementary strategic pillars:

- Preparing for the Phase 3 clinical trial on NFL-101, prior to a marketing authorization (MA) application, in line with the roadmap for the product's development.
- Holding discussions with potential partners in Europe, the United States and Asia.
- Progressing with the development plan for NFL-301, the drug candidate for reducing excessive alcohol consumption.

NFL Biosciences has a cash horizon through to the third quarter of 2025 and will continue to benefit from an organization with limited fixed costs. To continue developing NFL-101 and launch the development of NFL-301, NFL Biosciences may put in place additional financing which, that independently or combined, may come from (1) non-dilutive financing, (2) partnerships with pharmaceutical companies, and (3) capital increases.

About NFL Biosciences

NFL Biosciences is a biopharmaceutical company based in the Montpellier area which develops botanical drug candidates for the treatment of addictions. NFL Biosciences' ambition is to bring new, natural, safer and more effective therapeutic solutions to the entire world population, including low- and middle-income countries. Its most advanced product, called NFL-101, is a standardized, nicotine

free tobacco leaf extract protected by two patent families. NFL Biosciences intends to offer smokers who want to quit a natural, safe, easy-to-administer and personalized alternative. NFL Biosciences is also developing NFL-301, a natural drug candidate for the reduction of alcohol consumption and has a drug development project for the treatment of cannabis use disorder.

The shares of NFL Biosciences are listed on Euronext Growth Paris (FR0014003XT0 – ALNFL). Find out more at www.nflbiosciences.com

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