



Press release

NFL Biosciences reports its 2025 half-year results and provides an update on its development

- Additional studies and analyses confirming the excellent safety profile of NFL-101, its immunological action associated with smoking abstinence, and its rapid and sustained effects on brain regions involved in addiction
- Strengthening of the Scientific Advisory Board with world-renowned experts
- Financing: €3 million capital increase in May 2025 and €1.2 million in non-dilutive funding obtained in July 2025, extending the cash runway until Q1 2027
- Scientific advice from European agencies and the U.S. FDA expected in the coming days

Montpellier, France, October 16, 2025 – 5:45 pm CEST – NFL BIOSCIENCES (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company developing innovative botanical drugs for the treatment of addictions, today announces its half-year results for the period ended June 30, 2025, as approved by the Board of Directors on October 16, 2025, and provides an update on its clinical, industrial and financial developments.

Bruno Lafont, Chief Executive Officer and co-founder of NFL Biosciences, states: *“September 2025 marked a major milestone for NFL Biosciences, with the publication of the full results of the Phase 2 CESTO II trial in Nicotine & Tobacco Research, the official journal of the Society for Research on Nicotine and Tobacco (SRNT). This peer-reviewed publication, which validates the methodological robustness and relevance of our results, confirms NFL-101’s position as an innovative treatment for smoking cessation and highlights its unique approach based on a specific immunological response. We have strengthened our Scientific Advisory Board by welcoming internationally recognized experts and initiated a scientific collaboration with McLean Hospital, affiliated with Harvard Medical School. We now await the final feedback from the scientific advice procedures conducted with several European regulatory agencies and the U.S. FDA, which will enable us to finalize our development plan.”*

Update on first-half 2025 activity

Clinical progress

NFL-101, first-in-class treatment for smoking cessation

Positive results from an additional preclinical program confirming the excellent safety profile of NFL-101

NFL Biosciences conducted an extended toxicity program designed to assess the administration of higher doses of NFL-101, with daily administrations compared to the weekly administrations used in the previous program conducted prior to the start of clinical trials. The program also included genotoxicity and mutagenicity tests, performed at the maximum doses authorized by these tests. The toxicity study evaluated daily subcutaneous administration of increasing doses of NFL-101 in Sprague Dawley rats for 14 days. The maximum cumulative dose tested was 630 times higher than the cumulative dose administered to humans and did not induce any signs of systemic or local toxicity.

Results of the immunological analysis of the Phase 2 CESTO II trial confirming the efficacy of NFL-101

In the Phase 2 CESTO II trial, a secondary objective was to explore a potential association between the induction of anti-tobacco immunoglobulins (anti-tobacco IgG) and continuous smoking abstinence, in order to provide additional biological evidence supporting the behavioral observations based on abstinence measures. Continuous abstinence had already been confirmed using the urinary cotinine biomarker, while the increase in anti-tobacco IgG serves as a distinct immunological marker, reflecting the specific biological response triggered by the treatment. Immunogenicity tests performed at several time points confirmed a dose-dependent increase in anti-tobacco IgG levels—an effect not observed in the placebo group—indicating that NFL-101 has an intrinsic immunogenic effect. When comparing anti-tobacco IgG levels over time between continuously abstinent subjects and non-abstinent subjects, statistically significant differences ($p < 0.05$) were observed, with higher IgG levels in continuously abstinent individuals, regardless of the NFL-101 dose received. These findings suggest an association between the increase in anti-tobacco IgG following administration of NFL-101 and the maintenance of continuous abstinence. This association reinforces the evidence that the superior efficacy observed in terms of continuous abstinence is indeed attributable to the administration of NFL-101. These results mark the completion of the CESTO II data analysis and have been included in the scientific publication project.

Results of a new study conducted with the CEA providing further insight into the effect of NFL-101, highlighting its prolonged activity

Following the success of a first study conducted with the French Alternative Energies and Atomic Energy Commission (CEA), and with the objective of confirming the results obtained, further identifying the targeted brain regions and assessing a potential persistence of effects, NFL Biosciences entrusted the CEA with a second, more in-depth study based on its tobacco exposure mouse model. This new study demonstrates not only that NFL-101 acts precisely on the brain regions involved in addiction, but also that its effect occurs rapidly after administration and is maintained over time — an observation consistent with the clinical experience acquired in the Phase 2 CESTO II study.

Governance

The company has expanded its Scientific Advisory Board, which now includes international experts in addiction and immunology: Professor Scott Lukas (Harvard Medical School, USA), Professor Stuart Ferguson (University of Tasmania, Australia), Professor Bernard Le Foll (University of Toronto, Canada), and Professor Eric Tartour (European Georges Pompidou Hospital, France). This strengthened committee provides complementary expertise covering the neurobiology of craving, behavioral pharmacology and clinical immunology, ensuring the scientific robustness of NFL Biosciences' strategic decisions.

Finances

In May 2025, NFL Biosciences successfully completed a €3 million capital increase through the issuance of new shares subscribed by professional and retail investors.

Post-closing events

Publication of the CESTO II study results

In September 2025, NFL Biosciences announced the publication of the results of the Phase 2 clinical trial CESTO II, evaluating NFL-101 as a smoking cessation therapy, in the peer-reviewed international journal Nicotine & Tobacco Research, the official journal of the Society for Research on Nicotine and Tobacco (SRNT), published by the University of Oxford. The article, titled "[*Efficacy and Safety of NFL-101 as a Smoking Cessation Therapy: A Randomized Phase II Clinical Trial CESTO II*](#)", validates the robustness and relevance of the trial results. This publication demonstrates the recognition of CESTO II's findings by the international scientific community and further increases the global visibility of NFL-101 and NFL Biosciences.

Scientific collaboration

Also in September, the company entered into a strategic collaboration with McLean Hospital in the United States, affiliated with Harvard Medical School, to conduct research aimed at deepening the understanding of NFL-101's action on the central nervous system.

Governance

In July 2025, NFL Biosciences appointed Dr. Yannick Plétan as Chief Medical Officer. A pulmonologist and clinical pharmacologist with extensive experience at Sanofi, Pfizer, and Roche-Genentech, Dr. Plétan notably contributed to the development and launch of major smoking cessation therapies, including Champix® (varenicline). His appointment represents a key asset to lead the next clinical and regulatory stages of NFL-101's development in an international context.

Finances

Also in July 2025, NFL Biosciences secured its first non-dilutive funding totaling €1.2 million, adding to its recent capital increase, to support the continued development of NFL-101. This financing includes a €600,000 recoverable advance ("Aide à l'innovation") granted by Bpifrance, and €600,000 in medium-term bank loans from Société Générale and Banque Populaire, two of the company's long-standing banking partners.

Outlook

NFL Biosciences has initiated and conducted scientific advice procedures with several regulatory agencies, including the Belgian, Dutch, UK, and German authorities, as well as the U.S. Food and Drug Administration (FDA), as part of the development of NFL-101. These procedures covered all aspects of the product's development plan, up to the future marketing authorization applications (MAA). The company is awaiting the final feedback from these discussions and plans to communicate in the coming days.

First-half 2025 financial results

The 2025 half-year financial statements, prepared in accordance with French accounting standards, were approved by the Board of Directors on October 16, 2025. They were subject to a limited review by the Statutory Auditor, and the half-year report will be made available to the public on Friday, October 17, after market close.

Parent company financial statements (in euros)	June 30, 2025 (6 months)	June 30, 2024 (6 months)
Net revenues	-	-
Total operating income	158	40
EBIT	(2,121,162)	(896,065)
Financial income	(2,175)	42,779
Non-recurring income	-	-
Income tax	(319,615)	(121,777)
Net income	(1,803,721)	(731,509)
Shareholders' equity	1,820,389	2,288,261
Conditional advances	1,599,682	1,190,000
Intangible assets (patents)	170,195	163,813
Liabilities	1,003,080	1,530,916
of which financial liabilities	30,330	53,356
of which operating liabilities	972,750	1,477,560
of which prepaid income		
Cash and cash equivalents	2,928,269	3,546,153
Balance sheet total	4,423,152	5,009,176

NFL Biosciences did not generate any revenue or significant operating income during the six-month periods ended June 30, 2025 and June 30, 2024.

Operating loss amounted to (2,121) k€ as of June 30, 2025, compared with (896) k€ as of June 30, 2024. This increase in operating expenses reflects the work carried out during the period on the industrial organization project for the future manufacturing of NFL-101 doses, as well as complementary studies performed notably on the product's non-toxicity and mechanism of action.

Financial result amounted to (2) k€ in the first half of 2025, compared with 43 k€ in the first half of 2024. This decrease mainly reflects the lower interest rates on cash investments in capital-guaranteed accounts.

The Research Tax Credit (CIR) recognized over the period amounted to 320 k€, compared with 122 k€ in 2024.

As of June 30, 2025, the net loss stood at (1,803) k€, compared with (732) k€ as of June 30, 2024.

The company's cash position amounted to €2.9 million as of June 30, 2025, compared with €3.5 million as of June 30, 2024. Taking into account the non-dilutive financing obtained after the closing, the company's cash runway extends until the first quarter of 2027.

Total liabilities as of June 30, 2025 amounted to €1,003 thousand, including 30 k€ in medium-term financial debt with Société Générale and 973 k€ in trade payables, compared with a total of 1,531 k€ as of June 30, 2024. Refundable advances totaling 1,600 k€ correspond to the two Bpifrance recoverable advances granted in 2023, with the remaining balance of 410 k€ disbursed during the period. Repayment is scheduled through quarterly installments starting in December 2025.

About NFL Biosciences: www.nflbiosciences.com

NFL Biosciences is a biopharmaceutical company based in the Montpellier region of France, developing plant-based drug candidates for the treatment of addictions. NFL Biosciences' ambition is to bring new, safer and more effective natural therapeutic solutions to the entire world population, including low- and middle-income countries. Its most advanced product, NFL-101, is a standardized tobacco leaf extract protected by three patent families. NFL Biosciences intends to offer smokers wishing 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 disorders.

NFL Biosciences shares are listed on Euronext Growth Paris (FR0014003XT0 - ALNFL). The company is qualified as an "Innovative Company" eligible for FCPI investment. More information on www.nflbiosciences.com

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