



Press release

NFL Biosciences reports its 2026 half-year results and progress with its two immunotherapies for smoking and nicotine cessation

- **NFL-101 – immunotherapy aimed at reducing neuroinflammation:**
 - Biomarker results supporting a personalized medicine approach
 - Next step: discussions with the FDA and EMA to confirm the Phase 3 clinical development plan
- **NFL-102 – immunotherapy aimed at restoring neuroplasticity**
 - Successful manufacturing of a GMP-compliant clinical batch
 - Obtaining regulatory approvals to begin the TONIC Phase 2 trial
 - Launch of the TONIC study, consisting of Part A (the first 40 participants) and Part B (the next 270 participants), scheduled for November 2026
- **Positive initial results from the study conducted at McLean Hospital / Harvard Medical School on the effects of NFL Biosciences' immunotherapies on neurotransmitters**
- **Intellectual property portfolio expanded to five patent families, including two new applications filed in the first half of the year**
- **Cash position of €2.5 million as of June 30, 2026, and cash runway through the end of the first half of 2027, including funding for Part A of the TONIC study**

Montpellier, France, October 22, 2026, at 6:15 pm CEST – NFL Biosciences (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company developing immunotherapies for smoking and nicotine cessation, announces its financial results for the first half of 2026, as approved by the Board of Directors on October 22, 2026, and provides an update on progress with its two programs.

NFL Biosciences aims to broaden the therapeutic options available to smokers wishing to quit by developing approaches not yet available in smoking cessation: immunotherapy and patient selection using a biomarker predictive of response. These two approaches, which have profoundly transformed cancer treatment, are central to the development of NFL-101 and NFL-102.

Bruno Lafont, Chief Executive Officer and co-founder of NFL Biosciences, states: *"Tobacco is the leading preventable cause of cancer worldwide. Yet, while oncology benefits from immunotherapies and treatments guided by predictive biomarkers, smoking cessation drugs remain focused on nicotinic receptors. Our ambition is to bring the treatment of tobacco dependence into this new therapeutic era. With NFL-101 and NFL-102, we are developing two distinct immunotherapies, including a personalized approach aimed at identifying the smokers most likely to respond to treatment. The progress achieved brings us closer to this goal."*

NFL Biosciences has completed several previously announced milestones: manufacturing and quality control of the NFL-102 clinical batch, obtaining regulatory approvals to begin the Phase 2 trial, and presentation of scientific results at the scheduled conferences.

Two distinct and complementary immunotherapies developed in parallel

NFL-101 aims to reduce neuroinflammation in the brain. Its Phase 2 data and the identification of a biomarker associated with treatment response support a personalized medicine approach designed to target the smokers most likely to benefit. The program is intended to be the subject of a licensing agreement to advance its development into Phase 3.

NFL-102 aims to restore brain plasticity, which is involved in the lasting adaptations associated with addiction. NFL Biosciences is leading its development through clinical proof of concept. The TONIC study will evaluate its safety, efficacy and optimal dose, while also exploring the characteristics of patients who respond to treatment.

Both candidates are derived from standardized tobacco leaf extracts, with the same protein profile and different levels of low-molecular-weight compounds. They are designed to be administered as two subcutaneous injections one week apart. Their proposed mechanisms of action are being investigated in the Company's preclinical programs. By targeting distinct biological mechanisms, NFL-101 and NFL-102 could broaden the therapeutic options available.

NFL-101: advancing toward biomarker-guided patient selection

Post-hoc analyses of the Phase 2 CESTO II study identified a population more likely to respond to NFL-101, defined by a baseline anti-NFL-101 IgG1 level below 200 ng/mL. This population represented 57.2% of the 306 participants whose samples were available for analysis.

In this population, at the 100 µg dose, the four-week continuous abstinence rate, confirmed by urinary cotinine, reached 29.5% with NFL-101 versus 12.1% with placebo ($p = 0.016$). These results support the targeted development of NFL-101; the predictive value of the biomarker will need to be confirmed prospectively.

Analytical validation work on the specific IgG1 assay, conducted with the Georges Pompidou European Hospital, supports the development of a standardized test. Ultimately, a blood test could help physicians identify the smokers most likely to benefit from treatment. For a pharmaceutical partner, this approach offers the prospect of Phase 3 development targeting a population more likely to respond to treatment, while prospectively confirming the biomarker's predictive value.

A manuscript presenting these results is being prepared by a group of authors including experts from McLean Hospital / Harvard Medical School, the Centre for Addiction and Mental Health (CAMH) in Toronto and the Georges Pompidou European Hospital. Submission to an international peer-reviewed journal is planned for October 2026. Publication, following independent peer review, will broaden the scientific visibility of the results and support licensing discussions.

The Company intends to seek scientific advice from the FDA and EMA on the Phase 3 clinical development plan incorporating this biomarker for patient selection.

NFL Biosciences is seeking a partner to advance the Phase 3 development of NFL-101, incorporating this patient selection approach.

NFL-102: a compliant clinical batch and preparations for the Phase 2 TONIC study

The manufacturing of a clinical batch of NFL-102 in accordance with Good Manufacturing Practices (GMP), announced in June 2026, has been successfully completed. Quality control testing confirmed compliance with specifications. This milestone provides the material required for the TONIC study and validates the production chain from extract to finished product. NFL Biosciences works with Fareva for the extract, Meribel Pharma Solutions for the finished product and Eurofins for the main analyses, with manufacturing carried out on commercial production lines.

The Company recently obtained the necessary regulatory approvals from the French National Agency for Medicines and Health Products Safety (ANSM) and the Committee for the Protection of Human Subjects (CPP) to begin its Phase 2 TONIC study evaluating NFL-102 for smoking and nicotine cessation.

The TONIC study is expected to enroll 310 smokers in France in a multicenter, randomized, double-blind, placebo-controlled study. Its adaptive design will enable a dose to be selected progressively from three initial doses. The primary endpoint will be continuous abstinence over four weeks, confirmed by urinary cotinine.

Part A

An initial analysis will cover the first **40 participants**, located within the Eurofins Optimed Clinical Center (Gières, 38), and one dose will be eliminated based on safety and efficacy data reviewed, following unblinding, by an Independent Data Monitoring Committee (IDMC) and the Company.

The first participants are expected to be enrolled in November 2026, with this analysis planned for April 2027. These two milestones will be the subject of dedicated communications.

Part B

Following the enrollment of **150 additional participants** (50 per arm, randomized to either of the two retained doses or placebo), at about ten clinical centers in France, an interim analysis conducted by the IDMC will enable the most effective dose to be selected, while the other parties involved in the study remain blinded.

The study will then continue exclusively with the selected dose versus placebo, with the enrollment of **120 additional participants** (60 per arm, randomized to the selected dose or placebo).

A deeper understanding of the mechanisms of action

McLean Hospital / Harvard Medical School is conducting a preclinical microdialysis study in mice to measure neurotransmitters released in different brain regions and better understand the effects of the immunotherapies developed by NFL Biosciences.

Positive initial results were received in late September. These measurements will help link the biological effects observed to the brain circuits involved in dependence and withdrawal. They build on the brain imaging and proteomics research conducted at the French Alternative Energies and Atomic Energy Commission (CEA). The work is ongoing, and a dedicated announcement will be issued once the results have been consolidated.

An expanded patent portfolio and increased scientific visibility

The intellectual property portfolio now comprises five patent families. An application covering tobacco extract compositions and their use in the treatment of addictions was filed in January 2026. A second application, announced on May 25, concerns the use of the biomarker associated with NFL-101.

The Company's work was presented at the NIDA International Forum and the College on Problems of Drug Dependence (CPDD) conference in June, followed by the SRNT-Europe Conference in Paris and the Société Francophone de Tabacologie Congress in Rennes in September. The presentations covered the mechanisms of action, the NFL-101 biomarker and the TONIC protocol.

The CEA is finalizing a manuscript presenting brain imaging and proteomics results, with submission planned for October 2026. This research contributes to explaining the effects observed on brain activity and the biological pathways involved in addiction.

Upcoming scientific and clinical milestones

Expected timing	Milestone	Expected contribution
October 2026	Submission of manuscripts on the NFL-101 biomarker and the CEA's research	Independent peer review, followed by increased scientific visibility if published
November 2026	First participants enrolled in the Phase 2 clinical trial of NFL-102, TONIC	Start of the clinical evaluation of NFL-102
January–April 2027	Regulatory discussions and preparation of the NFL-101 Phase 3 study design	Clarification of how the biomarker will be incorporated and prospectively confirmed
April 2027	Analysis of the first 40 TONIC participants on NFL-102	Assessment of safety, guidance on dose selection and examination of initial efficacy signals

These timelines are indicative and depend on authorizations, recruitment and the progress of the work. The Company will prioritize securing a strategic partner to fund Phase 3 trials.

First-half 2026 financial results

The parent company financial statements, prepared in accordance with French accounting standards, were approved by the Board of Directors on October 22, 2026, and were subject to a limited review by the Statutory Auditor. The half-year financial report will be made available October 23.

Parent company financial statements as of June 30, 2026

Parent company financial statements in euros	June 30, 2026 (6 months)	June 30, 2025 (6 months)
Net revenues	-	-
Total operating income	3,115	158
EBIT	(1,988,297)	(2,121,162)
Net financial income/(expense)	(7,993)	(2,175)
Non-recurring income	-	-
Income tax	(469,523)	(319,615)
Net income	(1,526,767)	(1,803,721)
Shareholders' equity	(926,222)	1,820,389
Conditional advances	1,774,682	1,599,682
Intangible assets (patents)	171,524	170,195
Liabilities	3,994,505	1,003,080
<i>of which financial liabilities</i>		

<i>of which operating liabilities</i>	3,267,963	30,330
<i>of which deferred income</i>	726,542	972,750
Cash and cash equivalents	2,478,291	2,928,269
Balance sheet total	5,581,127	4,423,152

The Company did not generate any revenue during the period.

Operating loss amounted to €1,988 thousand, compared with €2,121 thousand in the first half of 2025. Net loss amounted to €1,527 thousand, compared with €1,804 thousand, with a Research Tax Credit of €470 thousand, compared with €320 thousand.

Expenditure notably covered additional CESTO II analyses, drug candidate characterization, the industrial development of NFL-102 and preparations for TONIC.

As of June 30, 2026, the cash position amounted to €2.5 million.

Based on its available cash and current forecasts, the Company estimates that its cash runway will enable it to fund its activities through the end of the first half of 2027, including Part A of the TONIC study, with initial results expected in April 2027.

The revision of the cash runway, previously announced as extending through the third quarter of 2027, reflects the inclusion of the costs of conducting Part A, in addition to the TONIC preparation costs already included in previous forecasts, notably completion of the clinical batch and submission of the application for authorization.

The Company is actively pursuing efforts to identify strategic and financial partners to support the continued clinical development of NFL-102 (Part B of the TONIC study) and the initiation of Phase 3 with NFL-101.

In addition, in March, NFL Biosciences obtained a €0.5 million loan from Bpifrance, with a 36-month repayment deferral. In April, the Company issued convertible bonds with a nominal value of €2.6 million to European investors, including Vester Finance. Subscribed at 92% of their nominal value, these bonds generated proceeds of €2.392 million, paid in full upon subscription. These financings notably support the development of NFL-102 and preparations for TONIC.

Governance

The Combined General Meeting held on June 17, 2026, approved all resolutions recommended by the Board of Directors. Detailed voting results are available on the Company's website.

About NFL Biosciences: www.nflbiosciences.com

NFL Biosciences is a biopharmaceutical company based in the Montpellier region of France, developing a portfolio of immunotherapies for smoking cessation and nicotine dependence. Its two drug candidates, NFL-101 and NFL-102, are derived from standardized tobacco leaf extracts and target distinct biological mechanisms. NFL-101 is being developed using a personalized medicine approach based on a biomarker associated with treatment response and is intended to be the subject of a licensing agreement for Phase 3. NFL-102 is being advanced to clinical proof of concept through the TONIC study. Both treatments are designed to be administered as two subcutaneous injections one week apart. The Company's intellectual property comprises five patent families.

NFL Biosciences shares are listed on Euronext Growth Paris (FR0014003XT0 – ALNFL).

Contacts

NewCap

Investor Relations / Media Relations

Mathilde Bohin / Jérémy Digel

Tel.: 01 44 71 94 94

E-mail : nfl@newcap.eu

NFL Biosciences

Bruno Lafont

Tél.: 04 11 93 76 67

E-mail : info@nflbiosciences.com