

NFL BIOSCIENCES: 2023 FULL-YEAR BUSINESS AND EARNINGS UPDATE

Promising results of the PRECESTO Phase 2a exploratory study

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

CESTO II clinical trial (phase 2b, underway) for the drug candidate NFL-101 for smoking cessation: top-line results to be released in July 2024

Pre-IND application filed with the FDA for NFL-301, a drug candidate to reduce alcohol consumption

NFL BIOSCIENCES (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company developing botanical drugs for the treatment of addictions, is reporting its full-year results for 2023, approved by the Board of Directors on March 27, 2024. On this occasion, NFL Biosciences looks back on the achievements from the past year, including the significant advances made with the studies concerning NFL-101, a product indicated for smoking cessation, and the pre-development stages for NFL-301, a product for the treatment of alcoholism.

Promising results for the PRECESTO clinical trial

PRECESTO is the second study after CESTO which highlights the effect of NFL-101 in terms of reducing smoking satisfaction.

PRECESTO was a placebo-controlled Phase 2a exploratory study, with a crossover covering two periods of 28 days each, including 34 smokers who did not wish to quit. Approved by the ANSM in November 2022, it was finalized this autumn.

The results¹ showed a significant and clinically relevant reduction in smoking satisfaction among smokers who do not wish to quit, with a more prolonged effect than expected. The observations revealed that the maximum effect of NFL-101 is at 28 days, i.e. the end of the observation period.

These promising results confirmed the therapeutic interest of NFL-101 administered on its own or in combination with nicotine replacement therapies, which reduce withdrawal symptoms. They also corroborate the results of the patent application filed in the United States in October 2022, increasing the probability of a patent being issued that would offer protection through 2042 at a minimum.

Progress with the CESTO II clinical trial

CESTO II is a multicentric, randomized, double blind and placebo controlled Phase 2b clinical trial over a total of 12 months, with 318 smokers who wish to quit. The trial is being conducted as follows:

This study's primary objectives are to select the best dose and assess the efficacy of NFL-101 versus placebo. The main criterion is continued abstinence for four weeks. Secondary criteria are also being studied, including continued abstinence for three months, six months, nine months and twelve months, continued abstinence at the end of the treatment for three months and six months, and continued abstinence during the last three months of the study. A number of exploratory criteria will also be analyzed.

The recruitment of subjects started in January 2022, gradually mobilizing a total of eight Clinical Investigation Centers (CIC) at CHU university hospital centers (Bordeaux, Clermont-Ferrand, Dijon, Lorient, Marseille, Montpellier, Poitiers and Rennes), as well as the Eurofins-Optimed research institute (Grenoble). The final and 318th randomization was carried out at the start of May 2023.

¹ See press release from October 5, 2024

In October 2023, and particularly following the PRECESTO results, the Company decided to maintain the blind during the planned 12 months of monitoring to maximize the use of all the data collected during the CESTO II study.

Taking into account the time required after the last follow-up visit of the last subject included, scheduled for early May 2024, to complete the audits at the clinical centers, validate the consolidated database, and transfer this database for statistical analysis by removing the blind, the communication of the top-line results is expected in July 2024.

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 French company leader in the development of pharmaceutical products administered orally, 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.

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's response is expected in the spring of 2024. NFL Biosciences will then be able to formalize the development plan and its budgeting.

The preparatory stages with this process have not required any significant outlays, while drawing up a development plan in line with the FDA's expectations will make it possible to reduce regulatory risks and ensure effective budget control.

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

In February 2023, NFL Biosciences set up a research partnership with the French Alternative Energies and Atomic Energy Commission (CEA) to study the mechanism of action of NFL-101 in an animal model. The results were presented at the end of January 2024².

This study highlighted a disruptive mechanism of action demonstrating:

- the ability of NFL-101 to reduce craving by 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.

Partnership strategy

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

The positive results announced during the year could accelerate the discussions that are already underway.

Under the partnership in India with THEMIS PHARMACEUTICALS, the activities are continuing to move forward with a view to obtaining an authorization for a clinical trial in India.

Governance further strengthened

On February 27, 2023, the Board of Directors appointed Dr Ignacio Faus, the Company's Chief Executive Officer, as Chairman of the Board of Directors, replacing Joël Besse (who had presented his resignation) for a period that will not exceed his term of office as a director, i.e. through to the end of the Ordinary General Shareholders' Meeting to be held in 2024 to approve the financial statements for the year ended December 31, 2023. On June 27, 2023, the shareholders approved the appointment of Ms Dominique Côté as an independent director. Her

² See press release from January 30, 2024

three-year term of office will expire at the end of the Ordinary General Shareholders' Meeting held in 2026 to approve the financial statements for the year ending December 31, 2025.

On November 28, 2023, the Board of Directors decided to renew, ahead of schedule, the terms of office of Mr Ignacio Faus as Chief Executive Officer and Mr Bruno Lafont as Chief Operating Officer for a period of five (5) years from May 19, 2024.

2023 full-year earnings

The annual financial statements for 2023 (January 1, 2023 – December 31, 2023), prepared in accordance with French GAAP, were approved by the Board of Directors during its meeting on March 27, 2024. They have been subject to an audit by the statutory auditors and the annual report will be published on March 29, 2024.

Corporate accounts (€)	Dec 31, 2023 (12 months)	Dec 31, 2022 (12 months)
Net revenues	-	-
Total operating income	200,011	22
EBIT	(4,230,422)	(3,083,170)
Financial income	118,554	182,831
Non-recurring income	-	39,025
Corporate income tax	(366,393)	(417,829)
Net income	(3,745,476)	(2,443,484)
Shareholders' equity	349,945	843,996
Conditional advances	1,190,977	72,977
Intangible assets (patents)	141,041	135,784
Liabilities	2,429,706	1,478,510
- Of which financial liabilities	62,174	83,256
- Of which operating liabilities	2,367,532	1,395,254
- Of which prepaid income		
Cash and cash equivalents	2,338,044	1,053,581
Balance sheet total	3,970,628	2,395,484

In 2023, NFL Biosciences recorded €200K of operating income. This corresponds to the operating grant awarded by Bpifrance (total amount of €200K). As the Company is still in the clinical trials development stage, it did not record any revenues during the last three years.

In line with the resources allocated to drive progress with the programs presented above, and the Company's operations, EBIT came to €(4.2)m for 2023, compared with €(3.1)m for the same period in 2022. The resources were allocated to finalize the PRECESTO study, conduct the study with the CEA and support progress with the CESTO II study. Payroll and social security contributions totaled €775K for four persons at December 31, 2023, compared with €722K for four persons at December 31, 2022.

NFL Biosciences recorded a research tax credit (CIR) of €369K, compared with €397K in 2022. In 2023, the Company secured the reimbursement of its 2022 research tax credit for the total amount requested in 2022.

Financial income and expenses for 2023 came to €119K, compared with €183K one year earlier, taking into account the remuneration from investments of cash surpluses. As a result, NFL Biosciences recorded €(3.7)m of net income over the period, compared with €(2.4)m at December 31, 2022.

At December 31, 2023, the Company had €0.4m of shareholders' equity and €2.3m of available cash. Cash and cash equivalents are linked primarily to the capital increase carried out at the end of January 2023 (€3.0m), as well as the advances granted by Bpifrance for the NFL-101 and NFL-301 clinical trials (€1.1m). In the third quarter of 2023, the Company received €550K of proceeds from the exercising of the BSA and BSPCE warrants in end-June and July 2023 for a total of €550K, as well as the first installment of the grant for the PRECESTO study for €140K. The resources available will enable the Company to finalize the CESTO II study.

Outlook for 2024

Dr. Ignacio Faus, Chairman and CEO: *“In 2023, and at the start of 2024, NFL Biosciences made significant progress with the development of its core project, NFL-101 for smoking cessation: the results of the PRECESTO clinical trial in autumn 2023, and the advances with the mechanism of action study of NFL-101 during the first quarter of 2024. The next milestone will be the CESTO II clinical trial results, which are expected in July 2024. Based on the results of our previous studies, we are confident about the success of this key stage in the development of NFL-101. Discussions with potential partners are ongoing and the review of the requirements for the upcoming Phase 3 clinical trial are being started.”*

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

- Accelerating the discussions already started with potential partners in Europe, the United States and Asia. Confidential Disclosure Agreements (CDAs) have been signed with various companies with a view to get deeper into confidential discussions with some of them.
- 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 with a potential partner.
- Moving forward with NFL-301, the drug candidate for reducing excessive alcohol consumption, with a view to the formalization of the development plan once we received the response of the Food and Drug Administration (FDA), which is expected over the coming weeks.

NFL Biosciences has a cash horizon through to the end of 2024 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, independently or combined, may come from (1) capital increases, (2) non-dilutive financing and (3) partnerships with pharmaceutical companies.

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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